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New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Re Medicated Feed Applications

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 210, 225, 226, 501, 510, 514, and 558

[Docket No. 77N-0076]

New Animal Drugs for Use in Animal Feeds; Definitions and General Considerations; Revised Procedures Re Medicated Feed Applications

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to revise the current procedures and requirements concerning conditions of approval for the manufacture of animal feeds containing new animal drugs. Incorporated in this proposal are the terms previously proposed defining the various medicated feed articles produced.

DATE: Comments by April 9, 1981.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: George Graber, Bureau of Veterinary Medicine (HFV-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4438.

SUPPLEMENTARY INFORMATION:

I. Terminology for Medicator Feeds

In the **Federal Register** of January 17, 1978 (43 FR 2526), the agency proposed revised definitions for articles used in the manufacture of medicated animal feeds. The period for comment on the proposal was extended to May 19, 1978. As proposed, the currently used terminology, "premix", "intermediate premix", "supplement" or "concentrate", and "complete feed", would have been replaced by Type A, Type B, Type C, and Type D medicated feed articles. The proposed changes were intended to eliminate the ambiguity that currently exists in medicated feed nomenclature.

The currently used definitions were promulgated by the agency in the **Federal Register** of July 19, 1964 (29 FR 10506), under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348), to establish the various types of food additives and animal feed products that were applicable to the use of drugs in animal feeds. The definitions were based on the safety considerations such as the concentration of the drug in each article, the intended use of the article, and the risk of harm to humans associated with ingesting the article by the animal or food derived from the animal.

Section 558.3 (21 CFR 558.3) lists and defines the feed additive articles as complete feed, feed supplement, feed concentrate, and feed premix. Ambiguities have arisen because these commonly used terms have different meanings in the animal feed industry. For example, a "concentrate" is a concentrated source of energy (e.g., certain basal feedstuffs such as corn, soybeans, or milo) to the animal scientist and many others in the industry. However, many in the feed and animal drug industry and the regulatory agencies use the term "concentrate" to mean a concentrated drug supplement. A drug concentrate is also known as an intermediate premix or custom premix that contains only drugs, vitamins, and minerals. Thus, a concentrate for feed is referred to by several terms, some of which have different meanings.

Similarly, a "supplement" is known by many in the agricultural industry as an article of feed that supplies protein, vitamins, or minerals to animal diets that are otherwise nutritionally complete. Others view a supplement as being a dilute medicated feed concentrate. The term may also be used to refer to a supplemental medicated feed application.

A premix refers to a concentrated mix of any ingredient normally added to animal feed. It thus includes drugs, nutrients, and other substances added for medicinal or nutritional purposes.

The 1978 proposal, among other things, more precisely defined the difference between an animal drug requiring an application to be approved under section 512(c) of the act (21 U.S.C. 360b(c)) and a regulation published under section 512(i) of the act (21 U.S.C. 360b(i)) and an animal feed requiring an application to be approved under section 512(m)(2) of the act (21 U.S.C. 360b(m)(2)). It changed the conditions for approval of intermediate premixes (Type B medicated feeds) from an NADA to a medicated feed application on the basis that such articles are medicated animal feeds. The document also proposed revised definitions of production classes of animals.

The agency is publishing a new proposal to redefine the various types of medicated feed articles to utilize terminology not subject to varying trade and government usage and interpretation and to identify more clearly those medicated feed articles requiring an approved new animal drug application (NADA) or medicated feed application. When the original terms in § 558.3 were promulgated, the American Feed Manufacturers Association (AFMA) suggested that the medicated feed articles be designated by letter. The agency has concluded that terms such as those suggested by AFMA provide a practical system for clearly identifying the various types of medicated animal feeds. The definitions designate the currently used medicated feed articles as Type A medicated article and Type B or Type C medicated feeds.

II. The Task Force

In June 1978, FDA formed a Medicated Feed Task Force composed of members representing the Bureau of Veterinary Medicine (BVM), Executive Director of Regional Operations (EDRO), Associate Commissioner for Regulatory Affairs (ACRA), and the Office of the Chief Counsel. The Task Force was to review and examine the existing medicated feed program and to explore and recommend ways to employ resources more efficiently.

The Task Force concluded that the existing program is the result of piecemeal policies affecting animal drugs resulting from application of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) (the act) enacted in 1938, as it evolved before and after the passage of the Animal Drug Amendments of 1968 (Pub. L. 90-399). For example, section 201(g) of the act (21 U.S.C. 321(g)), which defines the term "drug", does not distinguish between drugs intended for use in man or other animals, nor did section 201(p) of the act (21 U.S.C. 321(p)), which defines the term "new drug", distinguish between new drugs intended for use in man or other animals. Therefore, before enactment of the Animal Drug Amendments, new drugs intended for both man and other animals were subject to the preclearance provisions of section 505 of the act (21 U.S.C. 355).

In 1945, Congress added section 507 to the act (21 U.S.C. 357) requiring the agency to certify batches of drugs composed wholly or partly of any kind of penicillin. This section has been amended several times to include streptomycin, chlortetracycline, bacitracin, chloramphenicol, and their derivatives. Again, no distinction was made in these provisions between the use of these drugs in man or other animals. Under authority granted by section 507(c) of the act (21 U.S.C. 357(c)), however, the Commissioner of Food and Drugs exempted antibiotics that were added to animal feeds from the certification provisions if the antibiotics were labeled for specific

conditions of use that were published in the regulations.

From the mid-1940's medicated premixes have been marketed for the administration of drugs to animals in medicated feed. Until the effective date of the Animal Drug Amendments of 1968, the act provided no unique procedure under the act for the review and approval of animal drugs, including those for the manufacture of medicated animal feed by feed mills. Before a new drug could be manufactured into a medicated feed, an application for the manufacture of a medicated premix required approval. The holder of the premix approval was then required to supplement its application for each feed manufacturer requesting use of the drug.

The Food Additives Amendment of 1958 applied to food additives intended for both man or other animals. This amendment added section 201(s) to the act (21 U.S.C. 321(s)), which defines the term "food additive" as any substance the intended use of which results or may reasonably be expected to result, directly, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. Thus, any drug added to food or feed of an animal was a food additive, and any drug capable of causing residues in the edible products of the food-producing animal was also considered to be a food additive because the residue from such drug would constitute a food additive in the edible products. Such drugs placed on the market following enactment of the Food Additives Amendment of 1958 could not be legally marketed unless a food additive regulation was promulgated providing for the drug's safe use or the drug was generally recognized as safe and, for those uses approved after October 10, 1962, as effective.

Because animal drugs intended for use in animal feeds were subject to the preclearance provisions of three distinct sets of procedural requirements, their administrative and preclearance provisions were overlapping, unduly complex, and time consuming.

The Animal Drug Amendments of 1968 added a new section—section 512 (21 U.S.C. 360b)—to the act, in which were consolidated the various parts of the act that related to new drugs intended for use in animals, including those intended for use in animal feeds. Consequently, section 512 of the act provides for separate, distinct requirements regarding regulation of new animal drugs and animal feeds bearing or containing new animal drugs.

New sections 201(w) and 201(x) of the act (21 U.S.C. 321(w) and 321(x)) defining the terms "new animal drug" and "animal feed," respectively, were also added.

Even after passage of the Animal Drug Amendments, the medicated feed program continued to grow in a haphazard way. Exemptions from section 512(m) of the act resulted in feeds containing some carcinogenic drugs being exempt from preapproval requirements, whereas feeds containing some drugs with wide margins of safety are subject to only partial or no exemptions. This was compounded by inconsistencies in the exemptions among drugs and among uses of individual drugs. For example, a new animal drug in feed may be exempted for one species but not others, making the preclearance procedure confusing and difficult to enforce because marketing under the exempted use may be diverted to a nonexempted use.

It was against this background that the Medicated Feed Task Force met to evaluate the agency's past policies, consider current needs, and recommend new initiatives in the agency's medicated feed programs. The Task Force concluded that the current medicated feed program lacks focus. It recommended, among other things, that regulatory control of feeds containing new animal drugs that pose a potential risk to humans from residues should be strengthened, and control of feeds containing drugs that pose little risk to humans should be reduced, thereby better utilizing the limited resources of the agency. Requirements for approved medicated feed applications should be based upon the degree of risk from use of the drug either in terms of the toxicity of the drug itself or the concentration of the drug in a feed. FDA should approve such applications only after firms pass an inspection demonstrating their ability to manufacture feeds in compliance with current good manufacture practice regulations (21 CFR Part 225). The Task Force presented its report, entitled "Second Generation of Medicated Feeds," to the Commissioner of Food and Drugs, who announced its availability in the **Federal Register** of December 15, 1978 (43 FR 58634).

Following the Commissioner's decision to implement the recommendations of the Task Force to restructure the medicated feed program, the agency announced in the **Federal Register** of March 6, 1979 (44 FR 12208) that it was postponing action on the feed definitions proposal.

Since the release of the Task Force report and in response to comments on the report submitted by the public, additional revisions to the recommendations of the Task Force have been made by the agency. The revisions are consistent with the aims of the Task Force and the mandate of the agency to protect the public health.

III. Purpose of This Proposal

The purpose of this document is to:

1. Propose revisions in the current procedures and requirements concerning conditions of approval for the manufacture of animal feeds containing new animal drugs on the basis of the recommendations of the Medicated Feed Task Force.
2. Propose terms defining the various medicated feed articles produced.
3. Respond to comments made on the 1978 feed definitions proposal.
4. Respond to comments received on the Medicated Feed Task Force Report.
5. Announce the compliance (directed inspection) program.
6. Explain the implementation process and schedule of the new program.
7. Propose good manufacturing practice regulations for firms producing medicated feeds not requiring an approved medicated feed application.

IV. Drug Categories

The Task Force recommendations focused on maximizing public health protection by orienting the medicated feed program to the human risk potential of medicated feeds. Control is strengthened where the potential risk is greatest and lessened where the risk is minimal. The drugs administered in medicated feed are placed in three categories. The placement is subject to change by notice and comment rulemaking, based on review of existing or new safety data.

Where the potential for unsafe residues is the least, the level of use for the drug for subsequent manufacture of a medicated feed is least limited. Where the potential for drug residues is greatest from misuse, the level of use for the drug for subsequent manufacture of a medicated feed is more limited. Where the agency's concern about the safety of the drug is the greatest, the level of use for the drug for subsequent manufacture of a medicated feed will be the most limited.

The concentration of a medicated feed article exempt from the requirement of an approved medicated feed application is a function of its category and its highest continuous use level. The manufacture of a Type A medicated article will continue to require an approved new animal drug application. The manufacture of a Type B or Type C mediated feed from a Type A medicated article will require an approved medicated feed application. However, the use of a Type B or Type C medicated feed for further manufacture is exempt

from the requirement of an approved medicated feed application. The maximum (Type B medicated feed) exempt level for a Category I drug is 200 times the highest continuous use level; for a Category II drug, 100 times the highest continuous use level; and for a Category III drug, 50 times the highest continuous use level.

Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

Drugs in this category include: aklomide, ammonium chloride, amprolium with or without ethopabate, bacitracin (from bacitracin methylene disalicylate or zinc bacitracin), bambermycins, buquinolate, chlortetracyline, coumaphos, decoquinate, dichlorvos, erythromycin (thiocyanate salt), ethylenediamine dihydriodide, iodinated casein, nequinate, nystatin, oleandomycin, oxytetracycline, penicillin, penicillin with streptomycin, poloxalene, streptomycin, tylosin, virginiamycin, zoalene.

Category II—These drugs are subject to a withdrawal period at the lowest use level for at least one species for which they are approved.

Drugs in this category include: arsanilate sodium, arsanilic acid, butynorate, carbarsone, clopidol, famphur, hygromycin B, lasalocid, levamisole, lincomycin, monensin, neomycin, nicarbazin, nitrasone, novobiocin, phenothiazine, piperazine, pyrantel tartrate, robenidine, ronnel, roxarsone, sulfadimethoxine-ormetoprim, sulfaethoxypyridazine, sulfamethazine, sulfamerazine, sulfanitran with aklomide, sulfaquinoxaline, sulfathiazole, thiabendazole.

Category III—These drugs are regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern.

Drugs in this category include: carbadox, chlormadinone acetate, dimetridazole, furazolidone, ipronidazole, melengestrol acetate, nitrofurazone, nitromide.

The act does not explicitly provide for an exemption from approval for the direct manufacture of a medicated feed from a new animal drug (Type A medicated article), or for the manufacture of one medicated feed from another medicated feed. Section 512(a)(1) of the act requires that before a new animal drug can be approved for use in manufacturing a medicated feed, an application must be filed with FDA under section 512(b) of the act. The following information must be included in the application:

1. Full reports of investigations which have been made to show whether or not the drug is safe and effective for use;
2. A full list of the articles used as components of the drug;
3. A full statement of the composition of the drug;
4. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;
5. Such samples of the drug and of the articles used as components thereof, of any animal feed for use in on which the drug is intended, and of the edible portions or products (before or after slaughter) of animals to which the drug (directly or in or on animal feed) is intended to be administered, as FDA may require;
6. Specimens of the labeling proposed to be used for the drug, or in case the drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant;
7. A description of practicable methods for determining the quantity, if any, of the drug in or on food, and any substance formed in or on food, because of its use; and
8. The proposed tolerance or withdrawal period or other use restrictions for the drug if any tolerance or withdrawal period or other use restrictions are required in order to ensure that the proposed use of the drug will be safe.

Upon approval of an animal drug application, a regulation is published under section 512(i) of the act, which provides:

When a new animal drug application filed pursuant to subsection (b) is approved the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the **Federal Register** the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug.* * *

Before an animal feed bearing or containing a new animal drug can be approved, an application must be filed with FDA under section 512(m)(1) of the act, which provides the following:

Any person may file with the Secretary an application with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. Such person shall submit to the Secretary as part of the application (A) a full statement of the composition of such animal feed, (B) an identification of the regulation or regulations (relating to the new animal drug or drugs to be used in such feed), published pursuant to subsection (i), on which he relies as a basis for approval of his application with respect to the use of such drug in such feed, (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed, (D) specimens of the labeling proposed to be used for such animal feed, and (E) if so requested by the Secretary, samples of such animal feed or components thereof.

This document proposes to modify the current requirements for obtaining approval for the manufacture of medicated animal feeds by not requiring the submission of medicated feed applications for those drug uses where there are adequate data available to show that to do so will not compromise the public health. While FDA believes that there exists implied authority for the agency to waive unnecessary ministerial requirements of the act, it is currently seeking an amendment to section 512 of the act that will provide explicit statutory authority to grant such exemptions.

For each drug category an approved medicated feed application is not required for the use of Type B medicated feed for the subsequent manufacture of another Type B or a Type C medicated animal feed.

The drug categories set the maximum levels for each Type B medicated feed based upon the highest continuous use level, as follows:

Maximum concentration

Category	Type B
I	200X
II	100X
III	50X

(X = the multiple of the highest continuous use level on a drug-by-drug basis)

The term "highest continuous use level" means the highest feed dosage at which the drug is approved for continuous use (14 days or more) or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest level would govern under this definition.

Because of the exemptions from approved medicated feed applications available under these provisions, it is expected that the number of firms requiring approved medicated feed applications will be greatly reduced. This will provide regulatory focus on

those products of greatest human health concern through uniform application of criteria for exemption.

V. Proposed Definitions

In the light of the recommendations of the Medicated Feed Task Force, and the comments received on the report of the Task Force, the definitions proposed in 1978 have been reevaluated and are being revised. As previously stated, the revised definitions of medicated feed articles serve several purposes. First, they establish a clear separation between those medicated feed articles that constitute new animal drugs subject to approval under section 512(c) of the act and animal feeds subject to approval under section 512(m)(2) of the act. Second they serve to distinguish among the various kinds of medicated feed articles subject to approval under section 512(m)(2) of the act. Type A medicated articles constitute animal drugs; Type B and Type C medicated feeds constitute animal feeds containing new animal drugs.

A. *Type A medicated article.* Under the proposed new definitions, the most concentrated article will be designated as Type A. This is a drug premix for medicating animal feed. The article will be solely for use in the manufacture of other medicated animal feed articles (animal feed bearing or containing a new animal drug), and it will be limited to use solely in accordance with its published regulation. It will consist of a new animal drug for use in the manufacture of a medicated animal feed and is approved under section 512(b) of the act. It usually will include a diluent (carrier substance), and it must be further diluted with nutrient material to produce either a Type B or Type C medicated feed.

A proposed Type A medicated article is comparable to the present "feed additive premix". In the current regulations, a "premix" must be diluted so that not more than 100 pounds of the article is added to a basic feed to produce 1 ton of a complete medicated animal feed, and this feed must have been shown to be safe and effective in accordance with section 512(b) of the act for its labeled drug use. In such premixes, a large quantity of carrier substances is required. The premix is then mixed with nutrient feed ingredients to produce the medicated animal feed. The NADA for a Type A medicated article must include evidence that all Type B and Type C medicated feed manufactured from it are safe when used as directed. In addition, the NADA must include adequate and well-controlled investigations demonstrating that such Type C medicated feeds are effective whether manufactured directly or through a Type B medicated feed.

When the Type A article and the medicated feeds (Type B and Type C) manufactured from it have been shown to be safe and effective under their labeled conditions of use in accordance with the requirements of section 512 of the act and the applicable regulations, the NADA will be approved. Notice of the approval and any applicable restrictions and conditions of use will be published in the **Federal Register** in accordance with section 512(i) of the act (21 U.S.C. 360b(i)). Consequently, a Type A medicated article requires an approved NADA and must be shipped in accordance with section 512(a)(1) of the act and 21 CFR 510.7.

A Type A medicated article is defined as a new animal drug intended solely for use in the manufacture of Type B or Type C medicated feeds. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hulls, corn gluten) with or without other inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105(a) (21 CFR 514.105(a)).

Type B and Type C medictated feeds are animal feeds containing one or more drugs and a substantial quantity of nutrient ingredients. For the purpose of these regulations, a substantial quantity of nutrients includes vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 50 percent of the weight of the Type A medicated feed article. The manufacture of a medicated animal feed from a Type A medicated article requires an application approved under § 514.105(b).

The primary emphasis of the Task Force was to stress drug safety to humans as the major criterion for establishing conditions for approval of medicated feed applications. The safety of an animal drug in feed is a function of both the human risk potential associated with the drug and its concentration in a medicated feed. The human risk potential is the basis for the categorization of animal drugs used in feed. The Type B and Type C medicated feeds are designated in terms of drug concentration. The conditions for approval for their manufacture is a function of the category of drug and nature of the medicated feed as follows.

B. *Type B medicated feed.* The proposed Type B medicated feed will be an animal feed bearing or containing a new animal drug that is intended solely for further manufacturing of other medicated feeds (Type B or Type C). The Type B medicated feed will consist of a new animal drug(s) approved under section 512(b) of the act as a Type A medicated article, a carrier, and nutrients. A proposed Type B medicated feed will conform to the statutory definition of animal feed. Before the article can be fed to animals, however, it must be substantially diluted with a nutrient(s) to form a Type C medicated feed.

The Type B medicated feed will be similar to the present "feed concentrate." The definition of the Type B feed, however, has been revised to encompass intermediate premixes.

In recent years there has been a trend, particularly in the medicated feed industry, toward unit packaging. This precludes the need for weighing of the drug component by the subsequent mixer, thereby improving quality control by eliminating possible weighing errors, cross-contamination of open bags, and other handling and weighing procedures prone to errors. The Task Force anticipates that the same trend would occur in lower concentration medicated feeds if intermediate level mixers were provided the economic incentive. A Type B medicated feed and the conditions proposed for its approval are intended to accommodate and encourage this trend. The maximum concentration of a Type B medicated feed is 200 times the highest continuous use level for Category I drugs, 100 times the highest continuous use level for Category II drugs, and 50 times the highest continuous use level for Category III drugs. The 200X, 100X, and 50X factors are divisible into 2,000 pounds, and multiples thereof, which are batch sizes commonly used in the industry.

C. *Type C medicated feed.* A proposed Type C medicated feed will also be a medicated animal feed bearing or containing a new animal drug. It will be produced by substantially diluting a Type A medicated article or Type B medicated feed with other feed ingredients to a level for use that is covered by an approved NADA. A Type C feed may be offered as a complete feed, or when specified under 21 CFR Subchapter E, it may be fed top dressed or offered free-choice in conjunction with other animal feed to supplement the amimal's total daily ration.

The manufacture of Type B and Type C medicated feeds produced from a Type A medicated article is subject to the current good manufacturing practice regulations in 21 CFR Part 225. Where an approved medicated feed application is required such application shall include the following information:

1. Name and address of the applicant;

2. The registration number and last date of registration of each mill as

assigned pursuant to section 510 of the act;

3. Whether the submission is an original or supplemental application;

4. Identification of the drug(s) or Type A medicated feed article used by name, potency, and manufacturer;

5. The species of animal(s) for which the medicated feed is intended;

6. The form of feed to be produced, i.e., mash, meal, crumbles, pellets, liquid, or other;

7. Whether the feed is to be shipped in bag or bulk;

8. Whether the feed is a Type B or Type C feed;

9. Whether the feed is for sale or own use or both;

10. The generic or brand name of the medicated feed, name of the drug(s) and finished level in feed, and amount of drug(s) or premix per ton;

11. Identification of the regulation(s) in Subchapter E on which the request for approval of the medicated feed is based;

12. Whether the attached labeling is in draft or final printed form;

13. A commitment to establish and maintain the required program of sampling and assaying as follows:

a. For Type B medicated feeds, assays of the first three batches manufactured, followed thereafter by assay of representative samples of not less than 5 percent of the annual production of each Type B medicated feed produced. The samples shall be collected and assayed by approved official methods. When any batch does not assay within limitations, each subsequent batch shall be assayed until three consecutive batches are within limitations. Reports of assays shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

b. For Type C medicated feeds, an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

14. A statement of minimum and maximum assay variation permitted from the labeled amount of the drug;

15. Identification of the authorized agent;

16. Applicant's name, title, and signature of responsible individual, and date.

This document proposes a new § 558.4 *Medicated feed applications.* The use of any Type A medicated article (premix) in the subsequent manufacture of Type B or Type C medicated feeds must be the subject of an approved medicated feed application. Each drug approved for use in medicated feed is listed in tabular form under its appropriate category. The maximum drug concentrations for Type B medicated feeds are given along with their respective assay limits. The regulation states that under section 512(a)(1) of the act a new animal drug intended for use in the manufacture of an animal feed shall be deemed to be unsafe for such purposes, unless the consignee for the drug holds an approved medicated feed application. The types of feed and drug levels that will not require an approved medicated feed application are proposed as follows:

Category I Drugs—Type B and Type C medicated feeds manufactured from any Type B feeds containing up to 200 times the highest approved continuous use level.

Category II Drugs—Type B and Type C medicated feeds manufactured from Type B feeds containing up to 100 times the highest approved continuous use level.

Category III Drugs—Type B and Type C medicated feeds manufactured from Type B feeds containing up to 50 times the highest approved continuous use level.

The Task Force also recommended that generic labeling be permitted for the approval of Type B and Type C feeds. The generic labeling permits the use of one representative label for each drug for each use, permitting different brand names under the same approval for Type B and Type C medicated feeds. This change has already been placed into effect for Type C medicated feeds and is reducing the number of labels being submitted for approval.

Consistent with the agency's concern with utilizing its limited resources on drugs and drug levels of human health significance, the regulations covering current good manufacturing practice are revised to maintain the current requirements for use of drugs of public health significance and to reduce the requirements for use of drugs for which an approved medicated feed application is not required. Accordingly, Part 225 is amended to provide for a relaxation of the requirements for current good manufacturing practice where the drug or drug concentration is of less public health significance.

VI. Comments on the January 17, 1978, Proposal

In the light of the conclusions and recommendations of the Task Force, the January 17, 1978, proposal has been reevaluated. The agency received nearly 50 responses to the proposal from animal feed and drug manufacturers, associations, and individuals. The issues raised and the agency's response to each are as follows:

1. Four comments asked that an economic impact study be completed before finalizing the proposal. The comments expressed concern that implementation of the proposal would result in significant cost increases, particularly from an increased burden of paperwork. This could result in loss of marginally profitable product lines.

The proposed action was intended to reduce the preclearance requirements for animal drugs in feed. Specifically, at the present time Type B medicate feed applications (intermediate premixes) require approval under section 512(c) of the act as new animal drugs. The proposal places these articles in the category of animal feeds requiring approval under section 512(m) of the act. This change substantially reduces the kind of information required for approval and removes the requirement that an approval be published for each such article under section 512(i) of the act. Under these circumstances the agency stated in its proposal that the action did not contain a major proposal requiring preparation of an inflation impact statement. No factual information was submitted in the comments to refute this conclusion. Nevertheless, the agency has prepared a revised regulatory analysis assessment which is on file with the Dockets Management Branch. Also, see "X. Summary of Regulatory Analysis Assessment" below.

2. A number of comments requested FDA to provide additional opportunity for public participation, either through a public hearing or by reproposal, before finalizing the 1978 proposal.

In connection with the implementation of the Medicated Feed Task Force and in consideration of the comments received on the initial proposal, this proposal incorporates further revisions to the recommendations of the Task Force. Moreover, the report of the Task Force has been made publicly available for comment. Interested persons are again being provided an opportunity for comment through this proposal.

3. Comments were made on alleged changes in the conditions of use for certain drugs through the comment and rulemaking procedure. A number of comments addressed specific changes in the regulations allegedly altering their conditions of use.

The agency did not intend to change the conditions of use of new animal drugs through rulemaking procedures.

Each of the specific comments received alleging changes in conditions of use of new animal drugs has been evaluated and, where appropriate, revisions have been made in this proposal.

4. Two comments requested that the regulations be amended to include the criteria for exemption from the requirement of an approved medicated feed application.

This proposal sets forth the medicated feed application exemption criteria based upon human risk potential.

5. Several comments requested that "on-farm" mixers be exempt from the requirement of an approved medicated feed application.

The act does not provide a basis for the preferential treatment of on-farm mixers over commercial feed mills. If an establishment, be it a commercial mill or an on-farm mixer, chooses to manufacture medicated feeds that do not require an approved application, they must be produced from the appropriate concentration of a Type B medicated feed as given in proposed § 558.4(c). Conversely, if an establishment, whether a commercial mill or an on-farm mixer, chooses to manufacture feeds that exceed the exempted concentrations in § 558.4(c), then an approved application is required. An approved medicated feed application merely requires that a firm register and comply with current good manufacturing practice regulations (21 CFR Part 225). The agency will consider any suggestions relative to any authority under the act that could provide for alternate requirements for "on-farm" mixers.

6. A number of comments requested that animal drugs that are not new animal drugs be exempt from the requirements of section 512(m) of the act.

The agency agrees that section 512(m) of the act does not apply to other than new animal drugs. Each of the animal drugs named in proposed § 558.4(c) is a new animal drug and thus subject to the requirements of section 512(m) of the act.

7. It was suggested that the requirement of approved medicated feed applications for the use of each drug be abandoned in favor of a system of certification of feed mills.

The Medicated Feed Task Force considered this approach as a possible alternative to the current system of approval of medicated feed applications. Although the concept of certification appeared to be advantageous in reducing paperwork, it was rejected because there is no authority under the act for such a program.

8. Several comments expressed concern that the amendment to § 207.20 *Who must register and submit a drug list* appeared to require that animal feed manufacturers list their drugs as well as register under section 510 of the act.

The amendment proposed was not intended to impose a drug listing requirement. On the contrary, the amendment would place Type B medicated feeds under the exemption from drug listing. At the present time they are not exempt from listing. Under this proposal, the exemption from drug listing is retained, and the regulation provides a further exemption from registration for all firms except those manufacturing medicated animal feeds requiring approved medicated feed applications.

9. A comment asked that Part 225—Current Good Manufacturing Practice for Medicated Feeds, be revised in paragraph (b)(3) of § 225.58 *Laboratory controls* to change the words "each batch" to "each Type B medicated feed article". The change was requested for clarity and consistency with § 514.2(c)(6). It was requested that the requirement in the third sentence of paragraph (b)(3) be changed to reduce the number of batch assays from five to three when one is out of compliance. It was argued that if three consecutive assays are adequate to initially establish control, three should be sufficient to reestablish control.

FDA agrees and has adopted both changes.

10. A number of comments requested that § 510.110 *Animal feed labeling; collective names for feed ingredients* be revised to permit the use of the same collective names in the labeling of Type B medicated feeds as is currently permitted in the labeling of supplements of complete feeds.

On the basis of the recommendations of the Medicated Feed Task Force, this revision is being proposed. The requested revision would permit the latitude in the labeling of Type B medicated feeds as is currently enjoyed for the labeling of Type C medicated feeds. The use of collective names permits the manufacturer to select alternate feed ingredients having similar characteristics on a "least-cost" basis without the necessity for providing alternate labeling for each formulation change. This change will reduce the amount of paperwork otherwise generated by the submission of supplemental applications for each alternative label change. The same rationale exists for the use of collective names for Type B medicated feed as for Type C medicated feed (e.g., linear programming of formulations based upon availability and cost of ingredients).

11. The proposal added a new paragraph (m) to § 510.3 *Definitions and interpretations*, providing for definitions of various production classes of animals. Many of the comments objected to the setting of age and/or weight limitations for classes of animals by regulation. They argued that such designations should be used solely as guidelines because of variations in feeding programs, local custom, and customer preference. In addition, many comments and suggestions were submitted regarding the specific animal classes.

The agency agrees that the definitions provided should be considered to be guidelines rather than regulations, and this proposal sets them forth as such. Their purpose is solely to clarify classes of animals in relation to label directions for use of animal drugs. Additionally, certain changes have been made in the definitions on the basis of comments received.

12. Several comments objected to the requirement in § 514.1(b)(3)(v)(*b*) that a new animal drug application for approval to manufacture a medicated premix include representative labeling for Type B, C, and D medicated feed articles to be manufactured from the premix. Objections were based primarily on the inability of the premix manufacturer to anticipate all of the various labeling that might be used for the medicated feed.

This requirement is not new. Representative feed labeling has been required previously as part of a new animal drug application for a premix. Obviously the premix manufacturer will be unable to anticipate all labeling that might be used. However, representative or typical labeling provides useful information to agency reviewers as to how the feeds will be offered for sale. Moreover, section 512(b)(6) of the act requires such representative labeling to be included in a new animal drug application.

13. A number of comments objected to the requirement in § 514.1(b)(5)(x) as appearing to require stability data routinely on nondrug ingredients. Comments stated that unless the premix manufacturer tested the stability of every nutrient ingredient that might be mixed with his premix, a feed manufacturer could be prevented from incorporating nutrients not stability tested by the sponsor of the premix. They objected that it is unreasonable to require this kind of stability testing for the use of medicated premixes when it is not required for use in nonmedicated feeds.

FDA agrees that routine stability testing for nondrug ingredients should not be required. However, where a stability problem for a nondrug ingredient is known or suspected, stability data may be requested by the agency.

14. Several comments stated that the feed assay requirements should be the same whether or not the manufacture of a feed required an approved medicated feed application.

Section 225.58 *Laboratory controls* is being revised. As revised, the manufacture of medicated feeds that do not require an approved application does not require a schedule of assays to be conducted. As previously stated, the agency program proposes to require more stringent controls over drugs of greater public health significance. Consistent with this goal, current good manufacturing regulations, including the requirement for performing routine assays, are more stringent for feeds requiring approved medicated feed applications than for those that do not. The regulations being proposed will not require that routine assays be performed for feeds not requiring an approved application. However, when assays have been performed, including those by State Feed Control Officials, records shall be maintained and, where necessary, corrective action shall be taken and documented.

15. Comments requested that the assay requirements for Type B medicated feeds provide a greater assay range than assay requirements for Type A medicated articles.

Because the agency does not have adequate information on appropriate assay limits for Type B medicated feeds, it had established the same limits for Type B feeds as for Type A medicated feed articles. However, the agency may revise the limits set by this proposal upon receipt of sufficient information in response to this proposal.

16. A number of comments requested that the regulations provide for the submission of representative master formulas in the medicated feed application rather than specific master formulas for each batch variation of Type B medicated feed produced. The comments argued that master formulas are frequently revised to provide for changes in formulations based upon availability of alternate ingredients and production of least-cost formulation. The requirement of preapproval for each such formulation would discourage this practice, resulting in an increase in production cost.

The agency agrees that the industry should have the latitude to adjust feed formulas to meet changing needs. Firms are required under current good manufacturing regulations to maintain a Master Record File and batch production records. Under these circumstances, and consistent with the decision to permit the use of collective names in the labeling of feed ingredients (see comment number 10 above), the requirement of submission of master formulas is deleted from this proposal.

17. Other comments regarding the content of medicated feed applications were concerned with the possible use of a facilities and procedures file for multi-plant firms to eliminate repetitious submissions, identification of responsible positions rather than responsible persons, and the commitment to have the required assays done rather than designating a specific laboratory.

Based upon recommendations of the Medicated Feed Task Force, each of these suggestions has been adopted. Rather than requiring detailed information in applications, greater reliance will be placed on field inspection programs to ensure that firms are in compliance with current good manufacturing practice regulations (21 CFR Part 225).

18. Three comments objected to the use of the word "premix" in defining Type A medicated articles because the agency had stated that the word tends to be ambiguous and subject to misunderstanding. The comments also objected to reference to nutrient content as part of the definition of a Type A medicated article.

This proposal deletes the word "premix" from the definition. However, the dividing line between a new animal drug (Type A medicated article) as defined in section 201(w) of the act and an animal feed (Type B or Type C medicated feed) as defined in section 201(x) of the act, is based upon the presence of a substantial source of nutrients. Therefore, reference to nutrient content is an essential part of the definition.

19. Comments objected to the defining of Type B and Type C medicated feeds in terms of nutrient content, misuse, and potential for producing unsafe residues.

As previously noted, the nutrient content is a part of the definition of an animal feed in section 210(x) of the act. For the purpose of defining Type B medicated feeds, a substantial quantity of nutrients is an amount not less than 50 percent of the weight of the Type A medicated feed article from which it is manufactured. References to misuse and potential for unsafe residues are not a part of the revised definitions. However, the potential for unsafe residues is a factor in determining the maximum permitted drug level in a Type B medicated feed.

20. A comment stated that the regulations should permit the manufacture of a Type B medicated feed from two Type A medicated articles.

The regulations do not bar the manufacture of a Type B medicated feed from two Type A medicated articles provided that an application has been approved for the combination and the combination product was authorized by regulations under section 512(i) of the act.

21. Comments objected to the provision in the definition of a Type C medicated feed article that when fed free-choice in amounts not less than one-half pound per head per day, the article shall not produce unsafe residues in food-producing animals. The comments pointed out that numerous drugs are approved for free-choice feeding on the basis of less than one-half pound per head per day and that the restriction would in effect withdraw prior approvals.

The agency has determined that the definition need not include the one-half pound restriction. The need to set a minimum on the amount of feed to be offered free-choice is a matter to be addressed as a part of the conditions of approval for the Type A medicated article and where such a restriction is appropriate, it will be included in the regulation published under section 512(i) of the act describing the conditions of use of the drug.

22. Seven comments stated that the proposed definition of a Type D medicated feed article should not be limited to the sole ration, but should recognize that these diets are supplemented with drinking water and frequently with oyster shell, grit, salt, and minerals as well as roughage.

Because good nutritional practice often dictates the supplementation of a base ration with free-choice nutrients the definition has been so revised. In addition, the use of drinking water is also recognized in the revised definition. The Type D medicated feed article defined in the 1978 proposal is combined with the Type C medicated feed article in this proposal.

23. One comment was concerned that the regulations would not identify holders of approved Type B medicated feed applications.

Because a Type B medicated feed is not a new animal drug but is an animal feed bearing or containing a new animal drug, its approval is not required to be the subject of a regulation published under section 512(i) of the act. The agency believes that to require publication of approval of all Type B

medicated feeds would place an unnecessary burden on the agency and the regulated industry. Furthermore, because the use of a Type B feed does not require an approved medicated feed application, such identification would serve no useful purpose.

24. Nine comments stated that the proposal should continue to permit exemptions from the requirement of approved applications for the manufacture of medicated feeds covered by § 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.*

The agency does not agree. Section 558.15 was established to require and obtain the submission of appropriate data with which to evaluate the long-term effects of the use of subtherapeutic antibacterials in animal feed. The section was not intended to provide a basis for exemption from other requirements of the act. At the time the section was established many of the products subject to it were being marketed without the approval of medicated feed applications. Rather than address the status of such products at that time, the agency permitted their continued marketing only on an interim basis while the data required by § 558.15 were being obtained and evaluated. The agency cannot justify the continued manufacture of these medicated feeds without an approved medicated feed application. Therefore, if this proprosal is finalized, 180 days thereafter, under the provisions of § 558.4 as amended, the use of each drug or combination drug in the manufacture of a medicated feed must be the subject of an approved application pursuant to section 512(m) of the act. Alternatively, in the absence of any other regulation upon which a sponsor may rely, the agency would have no choice but to proceed against their use in the manufacture of medicated feed.

25. Numerous comments were received addressing the changes proposed in the various regulations listed in Subpart B—Specific New Animal Drugs for Use in Animal Feeds. The comments were concerned with editorial errors, failure to include certain approved sponsors or approved uses, and proper identification of Type C and Type D medicated feed articles.

Each of these comments has been considered, and appropriate revisions have been made. However, because the regulations involved are subject to ongoing amendments and changes and because this proposal causes a number of the comments to become moot, the individual comments are not discussed.

The revisions proposed in the medicated feed approval system will require significant changes in some of the current procedures and requirements. Currently, all firms manufacturing medicated animal feeds are required to register under section 510 of the act. The amended regulations will require only those firms manufacturing medicated animal feed requiring approved medicated feed applications to register.

A number of new animal drugs approved under section 512(b) of the act will become animal feed and meet the definition of an animal feed in proposed § 558.3(b)(2). This document proposes to delete these approvals from the existing regulations and deem such approvals to be for approved medicated feed applications. This action is to the benefit of the sponsors of these applications because they will no longer be required to list their drugs under Part 207; they may market their medicated feeds to customers not required to hold an approved medicated feed application; and they will no longer be required to submit periodic records and reports under § 510.300 (21 CFR 510.300).

Certain medicated feed articles have heretofore been permitted to be manufactured under a waiver from the requirement of an approved medicated feed application. This document proposes to replace all previously granted waivers with a categorizing of exemptions based upon factors of human safety. Therefore, approved medicated feed applications will be required for some medicated feed articles that were formerly exempt. To provide for the submission and approval of such medicated feed applications where none was previously required, the effective date for implementation of this proposal shall be 180 days following the date of publication of a final order based upon this proposal.

VII. Comments on the Task Force Report

Following the release of the Task Force Report, a number of comments were received by the agency. Based upon comments received, additional meetings and further discussions on the proposed medicated feed program, a number of modifications in the recommendations of the Task Force have been made. Points that were raised by the comments and the agency's responses are as follows:

1. Several comments questioned the authority of the agency to revoke existing exemptions from the requirement of an approved medicated feed application through notice and comment rulemaking procedure, when the exemption has been granted as a part of the conditions of approval of a new animal drug application.

Some exemptions resulted historically from a change in the new animal drug status of the article; others were granted on the basis of uniform criteria set forth in a 1971 Bureau of Veterinary Medicine memorandum for administrative waiver of the ministerial requirements of section 512(m) of the act. In the former case the agency took no affirmative action granting the waiver. In the latter case, where the waiver was granted on the bais of the 1971 memorandum, each approval published in the **Federal Register** publication stated that the memorandum constituted an interim agency policy that is under review. This proposal constitutes notice of termination of the interim policy. The criteria being proposed are in anticipation that the Congress will make explicit what the agency has considered implicit regarding the authority of the agency to waiver the ministerial requirements of section 512(m) of the act.

2. Comments were concerned that the Task Force implementation be placed into effect uniformly to ensure that the new requirements do not create competitive disadvantages in the manufacture and marketing of medicated feeds. Concern was also expressed that any revised labeling be implemented so as to coincide with date of registration of feeds in the various States.

The agency intends to place this program into effect uniformly 180 days following finalization of this proposal. In this manner no competitive advantages would be expected to occur.

3. One comment suggested that the category designation system of I, IIA, IIB, and IIC was confusing and should be replaced with categories I, II, III, and IV.

The agency has revised its initial recommendations to establish three categories of drugs (I, II, and III).

4. A comment requested that the medicated feed application be simplified by deleting the requirement that the supplier of the premix (Type A medicated article) be named in the application. In lieu of this requirement the comment proposed that the applicant include a commitment to purchase such articles only from approved suppliers.

The agency believes that the name of the sponsor of the premix is necessary in an application to ensure that suppliers of Type A medicated articles are in compliance by being registered and by holding approved applications for such articles. Feed manufacturers may identify alternate suppliers for the

Type A medicated articles they purchase.

5. A comments requested that collective names be permitted in the labeling of Type B medicated feed articles.

As was previously stated, the agency agrees with this comment and is providing for the use of collective names in the labeling of Type B medicated feeds.

6. A comment suggested that the definition of a Type B medicated feed article be revised to delete the word "substantially" in reference to the required dilution of a Type A medicated article to produce a Type B medicated feed article. It was pointed out that a number of medicated feed articles that are, infact, intermediate premixes may be produced with less than a substantial dilution.

The agency agrees and has revised the definition as previously discussed to encompass such articles.

7. A comment alleged that the manufacture of Type D medicated feed articles directly from Type A medicated articles is more likely to ensure the proper amount of drug in the finished feed, and hence less likely to result in residues, than producing a Type D feed from Type B or Type C medicated feed articles. The assumption is that intermediate steps in the manufacturing process accord greater opportunity for error in mixture and cross-contamination. It was requested that special consideration be given exempting on-farm mixers from the requirement of approved medicated feed applications.

The agency acknowledges that this may be so for the most modern mills having the most sophisticated equipment, whether on-farm or commercial feed mill. For the most part, however, the industry does not have the capability for precision mixing. Moreover, the magnitude for error is substantially increased when highly concentrated drugs are used. Special exemption for on-farm mixers is not provided for. As previously noted, the previously proposed Type D medicated feed article has been combined with the proposed Type D medicated feed article and constitutes a Type C medicated feed in this proposal. No data were submitted that would establish that the manufacture of these medicated feeds directly from a Type A medicated article would be more likely to ensure the proper amount of drug in the finished feed than when they are producted through the intermediate step of a Type B medicated feed. To manufacture feeds containing high risk drugs, in addition to obtaining an approved medicated feed application, the firm must register and comply with current good manufacturing practices. Without the capacity to comply with CGMP's, a firm should not be using high-risk drugs.

8. Several comments requested that the Task Force reconsider certain criteria for drug use approval to consider that potential risk based upon "intended use" rather than "drug concentration." It was stated that large-scale mixer-feeders using concentrated drug sources are less likely to cause edible products of treated animals to contain illegal drug residues than feeds from commercial manufacturers. An approach was suggested for such operations that would include separate regulations covering good manufacturing practices for mixer-feeders, require that they be certified for exemption from sections 510 and 512(m) of the act, and provide for revocation of certificates for repeat violators.

The agency believes that the concentration of drug permitted to be exempt for mixer-feeders should be controlled as previously discussed in comment number 7. above. Although the concept of certification for exemption from sections 510 and 512(m) of the act has merit, there is no authority under the act for such certifications.

9. A comment requested that the regulations include the maximum levels of Type C medicated feed articles.

The agency has revised the initial proposal to provide that the maximum of a Type B level of the drug will be that specified in the regulations published under section 512(i) of the act. The maximum of the Type C medicated feed will be the highest level of use specified in the regulation published under section 512(i) of the act.

10. Several comments requested that Category IV drugs be permitted a 20X exemption in order that certain customarily used on-farm mixer drugs continue to be available to mixer-producers.

Under the revised criteria, these drugs now in Category III will be available at 50X or below without the requirement of a medicated feed application.

11. Concern was expressed that firms having passed an inspection within the last year or two not be subject to another preinspection and that, under the implementation of the preinspection approval program, firms that fail the inspection be reinspected on an expedited basis and in any case in less than a 12-month period.

Firms that have passed inspection within the past year would not ordinarily be subject to immediate reinspection under the new proposed program. Reinspection of firms that have failed a prior inspection will occur as soon as practicable on the basis of the availability of agency resources.

12. Comments urged the use of State inspection involvement and thorough training to ensure uniform and broad implementation.

The agency agrees with these concerns and is taking a number of steps to ensure uniform implementation. These include the involvement of State agencies through contractual agreements with FDA to participate in the inspectional programs, and participation by State and Federal personnel in a comprehensive medicated feed training program.

VIII. Implementation Procedures

The Task Force recommended a major reordering and restructuring of the medicated feed program to focus on protection of the public from unsafe drug residues in the edible products of treated animals. It proposed that agency resources be directed toward the use of high-risk drugs and drugs in high risk concentrations in feed by:

(1) Requiring an approved medicated feed application under section 512(m) of the act for the manufacture of such a feed, and

(2) Approving such application only after an inspection of the manufacturing facilities of the applicant establishes that the firm is capable of manufacturing feeds containing high risk drugs or drugs in high risk concentration, in that the firm is operating in compliance with current good manufacturing practice (CGMPR). Manufacturers of medicated feeds will be inspected within a 3-year time period.

The directed inspections are intended to permit more efficient use of inspectional resources to determine whether medicated feed firms are in compliance with key CGMPR factors. During this inventory inspectional phase (directed inspection), which has already begun and will continue until this proposal is finalized, the agency will develop an inventory of firms in compliance with CGMPR's.

If the proposal is finalized, firms in compliance may apply for approval of medicated feeds requiring approval under section 512(m) of the act under a new medicated feed application to be developed and issued by the agency. Firms that fail the directed inspection will be denied approval of additional medicated feed applications unless corrective actions have been taken resulting in compliance with the CGMPR's. Additionally, the agency will evaluate each failure to determine whether further administrative and regulatory action should be initiated,

i.e., withdrawal of approval of applications, regulatory letter, seizure, injunction, prosecution. A firm failing inspection may either initiate immediate corrective action or may voluntarily request withdrawl of approval of its medicated feeds application(s) and cease manufacturing medicated feeds which require this approval.

The final regulation under this proposal will, if adopted, exempt from drug registration under section 510 of the act (21 U.S.C. 360) medicated feed manufacturers not requiring approved applications pursuant to section 512(m) of the act (21 U.S.C. 360b(m)). These firms will not be considered subject to the biennial inspectional requirements of the act, but will continue to be subject to all other provisions of the act.

IX. Summary of Amendments

The revisions proposed in the medicated feed approval system will require significant changes in some of the current procedures and requirements. The specific amendments proposed are as follows:

§ 207.10 *Exemptions for domestic establishents.* This section is amended to exempt from registration firms that do not require approved medicated feed applications for the medicated feeds they manufacture. Consistent with the recommedations of the Task Force, only firms manufacturing medicated feed articles that require an approved medicated feed application will be required to register under section 510 of the act. Currently, all firms manufacturing medicated animal feeds must register. This change should substantially reduce the number of firms currently subject to the 2–year inspectional obligation in section 510(h) of the act. It would not, however, preclude inspection by the agency.

§ 207.20 *Who must register and submit a drug list.* This section is amended in paragraph (a) to incorporate the new medicated feed nomenclature.

§ 210.3 *Definitions.* This section is amended to insert the revised definitions of medicated feed types into the regulations and to provide a cross-reference to the regulations regarding current good manufacturing practices.

Part 225—Current Good Manufacturing practice for Medicated Feeds. This part is amended by inserting the revised nomenclature and revised assay requirements. New §§ 225.120 through 225.202 are established for current good manufacturing practice for firms not producing medicted animal feeds requiring approved medicated feed applications.

Part 226—Current Good Manufacturing Practice for Medicated Premixes. This part is amended by inserting the revised nomenclature.

§ 501.110 *Animal feed labeling; collective names for feed ingredients.* This section is amended to provide for the new medicated feed nomenclature and to permit the use of collective names in the labeling of Type B medicated feeds.

§ 510.3 *Definitions and interpretations.* A new paragraph (m) is proposed to include the revised species and classes of food animals.

§ 510.7 *Consignees of new animal drugs for use in the manufacture of animal feed.* This section is revised in paragraph (b)(2) to provide for the conditions for exemption from the requirement of an approved medicated feed application from section 512(m) of the act in accordance with the provisions of § 558.4.

§ 514.1 *Applications.* This section is amended in paragraph (b) to include the revised nomenclature and provide for the submission of representative labeling for Type B medicated feeds.

§ 514.2 *Applications for animal feeds bearing or containing new animal drugs.* This section is completely revised and expanded to include the specific information to be submitted in medicated feed applications for Type B and Type C approvals.

§ 514.112 *Return of applications for animal feeds bearing or containing new animal drugs.* This section was formerly covered by § 558.4. It has been transferred and updated without substantive change.

§ 558.3 *Definitions and general considerations applicable to this part.* This section has been completely revised. Each of the types of medicted feed articles are defined, and the criteria for their exemption from the requirement or an approved medicated feed application are set forth.

§ 558.4 *dMedicated feed applications.* A new section is proposed to set forth the provisions for the approval of medicated feed applications. It cites the requirement in the act that an application is required to include a reference to the regulation on which the approval relies. In order that these requirements be inclusive of all currently marketed medicated articles, this section provides that in addition to the specific regulations in Part 558, Subpart B, §§ 510.515, 558.15, and 558.20 may provide a basis for such reference. The section describes the categories and lists the drugs in each category. The listing includes the maximum level of Type B medicated feeds and the assay limits for each. In some instances specific assay limits could not be found in agency files. If any interested persons find these assay limits inappropriate, they are invited to submit data justifying any requested revisions.

§ 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed on animals.* Paragraph (g) is amended to include the revised nomenclature and to delete a provision that intermediate premixes produced from premixes in compliance with this section need not submit applications for their approval. This section was promulgated in the **Federal Register** of April 20, 1973 (38 FR 9811) requiring that certain data be submitted to justify the continued use of such drugs. Each drug sponsor was required to submit commitments to carry out the necessary studies. The regulation was amended in the **Federal Register** of February 25, 1976 (38 FR 8282) identifying each product and sponsor that complied with the commitment to provide required data. As amended, paragraph (g)(2) of the section exempted from the submission of applications and data the manufacturer of intermediate premixes, provided that the intermediate premixes were produced from premixes in compliance with the section.

Because such articles are redefined in this proposal as Type B medicated feeds, they will be subject to section 512(m) of the act, and approved medicated feed applications will be required for their manufacture. This will ensure equitable and uniform requirements for the manufacture of all Type B medicated feeds. Because the exemption was granted under notice and comment rulemaking procedure, the same procedure is being used for its revocation.

§ 558.20 *Drugs used in medicated feeds before January 1, 1958 which are not otherwise listed; interim listing.* A new section is proposed to include reference to drugs in medicated feeds not covered by specific regulations. The listing of these drugs does not alter their current status under the act, but does provide a basis for their continued use subject to approval of medicated feed applications under procedures described in § 558.4.

Part 558, Subpart B—Specific New Animal Drugs for Use in Animal Feeds. This subpart is republished with the following changes:

1. The revised nomenclature is added.

2. Conditions for waiver from the requirements of section 512(m) of the act are revoked. These conditions are included in § 558.4.

3. Assay limits are revoked. These are also covered by § 558.4.

4. A number of new animal drug sponsors listed pursuant to section 512(i) of the act are deleted. Under the revised

definitions these articles constitute animal feeds because they meet the definition of an animal feed in proposed § 558.3(b)(2). This document proposes to delete these listings from the existing regulations and deem such approvals to be approved medicated feed applications. This action is to the benefit of the sponsors of these applications because they will no longer be required to list their drugs under Part 207 (21 CFR Part 207); they may market their medicated feed articles to customers not required to hold an approved medicated feed application; and they will no longer be required to submit periodic records and reports under § 510.300 of the regulations.

5. Regulations covering drugs approved prior to August 1, 1969 for use in feed which were the subject of regulations published under the Food Additives Amendment of 1958 did not identify the sponsors of such articles. This proposal adds the sponsors of the food additive petitions for those drugs when the regulations were first promulgated under the Food Additives Amendment. Any other persons not so identified will be added to the final regulations if they respond in writing to this proposal identifying their approval by NADA number and approval date.

Currently, all firms manufacturing medicated animal feeds are required to register under section 510 of the act. The amended regulations will require only those firms manufacturing medicated animal feed requiring approved medicated feed applications to register.

Certain medicated feed articles have heretofore been permitted to be manufactured under a waiver from the requirement of an approved medicated feed application. This document proposes to replace all previously granted waivers with a categorizing of exemptions based upon factors of human safety. Therefore, approved medicated feed applications will be required for some medicated feed articles that were formerly exempt. To provide for the submission and approval of such medicated feed applications where none was previously required, the effective date for implementation of this proposal shall be 180 days following the date of publication of a final order based upon this proposal.

In compliance with Executive Order 12044 on Improving Government Regulations, and in accordance with Department (HHS) guidelines, FDA has asessed the economic impact of this rulemaking. Based on this assessment, FDA has determined that a Regulatory Analysis, as described in E.O. 12044, is not required. Following is a summary of the results of the Regulatory Analysis Assessment. A copy of the complete Regulatory Assessment is on file with the Dockets Management Branch, Food and Drug Administration.

X. Summary of Regulatory Analysis Assessment

FDA estimated the direct costs to industry and to the agency of the proposed restructured medicated feeds program for the 3-year transition phase and for subsequent years. In the estimated transitional phase, industry will incur net estimated startup costs of $3.0 million ($1.0 million annually). This includes one-time costs to submit applications for 26 previously exempt drugs. It also includes transitional phase savings because exemptions for drugs in newly-defined risk-by-feed-type categories and the generic labeling provision will reduce the number of "business as usual" applications.

The transitional phase impact on FDA will be $1.0 million ($0.3 million annually). This includes the inspection cost increment over present costs of inspections assuming that FDA will inspect all medicated feed establishments in its present inventory during the 3-year transitional phase, and that the agency will be successful in implementing a directed compliance program that significantly reduces the duration of inspections. It also includes the cost of processing applications for the previously exempt drugs and a saving on handling "business as usual" applications. (It is also possible to estimate the FDA inspection cost impact against the hypothetical baseline of full implementation of the existing statutory biennial inspection requirement. On this basis, FDA would have significant "savings" in the transition phase.)

Estimated Annual Net Costs and Savings[a] of the Proposed Medicated Feeds Program

[In millions of dollars]

Cost component	Transitional phase		Ongoing phase	
	Industry	FDA	Industry	FDA
Submision of applications for previously exempt drugs in feeds	1.53	0.11		
New submissions	(0.54)	(0.04)	(0.54)	(0.04)
Inspections[b]		0.25		(0.19) to 1.28
Net cost or savings	0.99	0.32	(0.54)	(0.23) to 1.24

[a] Savings expressed in parentheses.
[b] The range of impacts reflects low and high estimates of establishments in the FDA official inventory.

After the transition phase, it is estimated that the medicated feeds industry will save $0.5 million annually. In the ongoing period of the restructured program the estimated range of impact on FDA is from savings of $0.2 million annually to costs of $1.2 million annually, depending on the number of establishments that will require biennial inspection.

The regulatory analysis assessment discusses possible industry adaptations to the restructured program.

The agency has determined pursuant to 21 CFR 25.24(b)(12) and (d)(13) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Parts 207, 210, 225, 226, 501, 510, 514, and 558 be amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. Part 207 is amended in § 207.10 by revising paragraph (f) to read as follows:

§ 207.10 Exemptions for domestic establishments.

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(f) Persons who use drugs to manufacture Type B or Type C medicated animal feed except persons required under the act and its regulations to hold an approved medicated feed application to possess and use a drug or animal feed bearing or containing the drug.

PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS: GENERAL

2. Part 210 is amended by revising the title of the part as set out above and in § 210.3 by revising paragraph (b)(13) and (14) to read as follows:

§ 210.3 Definitions.

* * * * *

(b) * * *

(13) The term "medicated feed" means any Type B or Type C medicated feed as defined in § 558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this chapter.

(14) The term "medicated premix" means a Type A medicated article as

defined in § 558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this chapter.

* * * * *

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

3. Part 225 is amended:

a. In § 225.1 by revising paragraph (b), to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(b)(1) The provisions of this part set forth the criteria for determining whether the manufacture of a medicated feed is in compliance with current good manufacturing practice. These regulations shall apply to all types of facilities and equipment used in the production of medicated feeds, and they shall also govern those instances in which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated. In such cases, the medicated feed shall be deemed to be adulterated within the meaning of section 501(a)(2)(B) of the act, and the nonmedicated feed shall be deemed to be adulterated within the meaning of section 402(a)(2)(D) of the act.

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed application is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which approved medicated feed applications are not required.

b. In § 225.58 by revising paragraph (b)(1) and (2), to read as follows:

§ 225.58 Laboratory controls.

* * * * *

(b) * * *

(1) For Type C medicated feeds, an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

(2) For all Type B medicated feeds, assays of the first three batches manufactured, followed thereafter by assay of representative samples of not less than 5 percent of the annual production of each Type B medicated feed produced. The samples shall be collected and assayed by approved official methods. When any batch does not assay within limitations, each subsequent batch shall be assayed until three consecutive batches are within limitations. Reports of assay shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

* * * * *

c. By adding new Subpart F consisting of §§ 225.120, 225.130, and 225.135, to read as follows:

Subpart F—Facilities and Equipment

Sec.
225.120 Buildings and grounds.
225.130 Equipment.
225.135 Work and storage areas.

Subpart F—Facilities and Equipment

§ 225.120 Buildings and grounds.

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

§ 225.130 Equipment.

Equipment shall be capable of producing a medicated feed of intended potency, safety and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for its intended purpose. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

§ 225.135 Work and storage areas.

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of medicated feed.

d. By adding new Subpart G consisting of §§ 225.142, 225.158, and 225.165, to read as follows:

Subpart G—Product Quality Assurance

Sec.
225.142 Components.
225.158 Laboratory assays.
225.165 Equipment clean-out procedures.

Subpart G—Product Quality Assurance

§ 225.142 Components.

Adequate procedures shall be established and maintained for the receipt, labeling, storage, and use of all medicated feed articles intended for use in manufacturing medicated feeds to aid in assuring their identity, strength, and purity. All drug components must be used in accord with the labeled directions for use. Packaged drugs in the storage areas shall be stored in their original closed containers. Bulk drugs shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. An accurate inventory record shall be maintained for each drug component and shall be reconciled with production records each day the drug component is used in the production of medicated feeds. Significant discrepancies must be investigated and appropriate action taken immediately.

§ 225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State Feed Control Officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately and such records shall be maintained on the premises for a period of one year.

§ 225.165 Equipment clean-out procedures.

Adequate clean-out procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

e. By adding new Subpart H consisting of § 225.180, to read as follows:

Subpart H—Labeling

Sec.
225.180 Labeling.

Subpart H—Labeling

§ 225.180 Labeling.

Medicated feed that is mixed for further distribution shall be accompanied by appropriate labeling. Such labeling shall identify the medicated feed and provide the user with adequate directions for use,

including appropriate withdrawal and other warning or caution statements.

f. By adding new Subpart I consisting of § 225.202, to read as follows:

Subpart I—Records

Sec.
225.202 Formula, production, and distribution records.

Subpart I—Records

§ 225.202 Formula, production, and distribution records.

Where applicable, records after the last date of shipment of the medicated feed identifying the formulation, date of mixing, and distribution of the medicated feed shall be maintained for one year. Such records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed and to reconcile drug component usage against the inventory.

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

4. Part 226 is amended by changing the term "medicated premixes" to "Type A medicated article(s)" wherever it appears.

PART 501—ANIMAL FOOD LABELING

5. Part 501 is amended in § 501.110 by revising paragraph (a)(1) to read as follows:

§ 501.110 Animal feed labeling; collective names for feed ingredients.

(a) * * *

(1) The animal feed is a Type B or Type C medicated feed as defined in § 558.3 of this chapter and is intended solely for animal use.

* * * * *

PART 510—NEW ANIMAL DRUGS

6. Part 510 is amended:

a. In § 510.3 by adding new paragraph (m), to read as follows:

§ 510.3 Definitions and interpretations

* * * * *

(m) The following definitions of production classes of animals are to be considered as a guideline for use in animal drug labeling:

(1) *In poultry.* (i) "Broiler chickens" and "fryer chickens" are synonymous and denote chickens marketed for meat purposes only, usually at 6 to 9 weeks of age.

(ii) "Roaster chickens" are chickens marketed for meat purposes only, usually at 9 to 14 weeks of age.

(iii) "Replacement chickens" are chickens raised for the purpose of replacing breeding and laying chickens.

(iv) "Laying chickens" are chickens maintained for the purpose of producing eggs for food only.

(v) "Breeding chickens" are chickens raised for the purpose of producing eggs for hatching only.

(vi) "Fryer-roaster turkeys" are turkeys marketed for meat purposes only, usually at 12 to 17 weeks of age.

(vii) "Young hen or tom turkeys" are turkeys marketed for meat purposes only, usually at 17 to 26 weeks of age.

(iii) "Replacement turkeys" are turkeys raised for the purpose of replacing breeding turkeys only.

(ix) "Breeding turkeys" are turkeys maintained for the purpose of producing eggs for hatching only.

(2) *In swine.* (i) "Breeding swine" are swine used for reproduction.

(ii) "Prestarting swine" are swine that weigh up to 20 pounds.

(iii) "Starting swine" are swine that weigh from 21 to 40 pounds.

(iv) "Growing swine" are swine that weigh from 41 to 100 pounds.

(v) "Developing swine" are swine that weigh 75 to 126 pounds.

(vi) "Finishing swine" are swine that weigh between 100 to 125 pounds to market weight.

(3) *In ruminants*—(i) Cattle.

(*a*) "Calves" are cattle from birth to 8 months of age.

(*1*) "Vealers" are cattle intended for slaughter which have subsisted largely on milk or milk replacers and are usually less than 4 months of age and generally have a live weight less than 400 pounds.

(*2*) "Slaughter calves" are those from 3 to 8 months of age which are inteded for slaughter or for stocker or feeder cattle.

(*3*) "Replacement calves" are those intended for breeding purposes only.

(*b*) "Stocker and feeder cattle" are those intended for feedlots or slaughter only.

(*c*) "Feedlot cattle" are those maintained in feedlots and intended for slaughter.

(*d*) "Breeding cattle" are those intended for reproduction purposes.

(*1*) "Replacement heifers" are females prior to first parturition.

(*2*) "Replacement bulls" are males, 8 to 14 months of age.

(*3*) "Breeding cows" are females beyond first parturition.

(*4*) "Breeding bulls" are males, 14 months of age and older.

(*e*) "Lactating dairy cows" are cows of dairy or dual purpose breeds that produce milk intended for human consumption.

(*f*) "Non-lactating cows or dry dairy cows" are cows of dairy or dual purpose breeds that temporarily are not producing milk.

(ii) Sheep:

(*a*) "Lambs" are sheep from birth to 14 months of age.

(*1*) "Replacement lambs" are those intended for breeding purposes only.

(*2*) "Feedlot lambs" are those maintained in feedlots and intended for slaughter.

(*b*) "Breeding sheep" are those of breeding age used primarily for reproduction purposes.

b. In § 510.7 paragraph (b)(2) is revised to read as follows:

§ 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

* * * * *

(b) * * *

(2) When the use of such drug in the manufacture of an animal feed has been exempted from the requirements of section 512(m) of the act in accordance with the provisions of § 558.4 of this chapter.

PART 514—NEW ANIMAL DRUG APPLICATIONS

7. Part 514 is amended:

a. In § 514.1 by revising paragraphs (b)(3) (v)(*b*) and (vii)(*a*) and (b)(5)(x), to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(3) * * *

(v) * * *

(*b*) Representative labeling proposed to be used for Type B and Type C medicated feeds containing the new animal drug.

* * * * *

(vii) * * *

(*a*) A description of practicable methods of analysis of adequate sensitivity to determine the amount of the new animal drug in its final dosage form including Type B and Type C medicated feeds and in drinking water should also be included. Methods should be included for any Type A medicated article. Where two or more active ingredients are included, methods should be quantitative and specific for each active ingredient.

* * * * *

(5) * * *

(x) A complete description of, and data derived from, studies of the stability of the new animal drug, including information showing the suitability of the analytical methods used. A description of any additional stability studies underway or planned. Stability data for the finished dosage

form of the new animal drug in the container in which it is to be marketed, including any proposed multiple dose container, and, if it is to be put into solution at the time of dispensing, for the solution prepared as directed. If the new animal drug is intended for use in the manufacture of Type B or Type C medicated feed as defined in § 558.3 of this chapter, stability data shall be derived from studies in which representative formulations of the medicated feed articles are used. If the data indicate that an expiration date is needed to preserve the identity, strength, quality, and purity of the new animal drug, the applicant shall propose such expiration date. If no expiration date is proposed, the applicant shall justify its absence.

* * * * *

b. By revising § 514.2, to read as follows:

§ 514.2 Applications for animal feeds bearing or containing new animal drugs.

(a) Applications to be filed under section 512(m) of the act shall be completed, signed, and submitted in triplicate in the form described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B or Type C medicated feed shall include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill.

(3) Whether the submission is an original or supplemental application.

(4) Identification of the drug(s) or Type A medicated article used by name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal, crumbles, pellets, liquid, or other specified form.

(7) Whether the feed is to shipped in bag or bulk.

(8) Whether the feed is a Type B or Type C medicated feed.

(9) Whether the feed is for sale or for own use (not for sale).

(10) The generic labeling of the medicated feed and level of the drug(s) in the finished feed, and the amount of Type A or Type B medicated feed per ton contained therein.

(11) Identification of the regulation(s) in Subchapter E of this chapter on which approval relies.

(12) Sample generic labeling representative of each intended use as stated in the claim. Each generic label shall include the claim, drug level, mixing directions, feeding directions, caution and/or warning statements and any other special directions required by the published regulation. This shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(13) A commitment to establish and maintain the required program of sampling and assaying as follows:

(i) For Type B medicated feeds assays of the first three batches manufactured, followed thereafter by assay of representative samples of not less than 5 percent of the annual production of each Type B medicated feed produced. The samples shall be collected and assayed by approved official methods. When any batch does not assay within limitations, each subsequent batch shall be assayed until three subsequent batches are within limitations. Reports of assays shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

(ii) For Type C medicated feeds, an assay of the first batch manufactured, followed thereafter by two samples at periodic intervals during the calendar year. If a medicated feed contains a combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested. Reports of assays shall be kept on the premises for not less than 1 year after the last date of shipment of the assayed medicated feed.

(14) A statement of the minimum and maximum assay permitted from the labeled amount of the drug.

(15) Identification of the agent authorized to act on behalf of applicant.

(16) The applicant's name, responsible individual's title and original signature, and date.

(c) Upon approval, one copy of the application will be signed by an authorized employee of the Food and Drug Administration designated by the Commissioner, and it will be returned to the applicant.

c. By adding new § 514.112, to read as follows:

§ 514.112 Return of applications for animal feeds bearing or containing new animal drugs.

Applications submitted pursuant to § 514.2 will be returned to the applicant if such applications are incomplete or inaccurate or do not contain an identification of the applicable regulation(s). These regulations, published pursuant to section 512(i) of the act, are found in Part 558 of this chapter, and are the basis on which approval of the application relies, as required by § 514.2(b)(11).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

8. Part 558 is amended:

a. By revising § 558.3, to read as follows:

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) A "Type A medicated article" is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of an animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn gluten) with or without other inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105(a) of this chapter.

(2) A "Type B medicated feed" is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 50 percent of the weight of the Type A medicated article. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of a Type B medicated feet is 200 times the highest continuous use level for Category I drugs, 100 times the highest continuous use level for Category II drugs, and 50 times the highest continuous use level for Category III drugs. The term "highest continuous use level" means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest level would govern under this definition. The manufacture of a Type B medicated animal feed from a Type A medciated article requires an application aproved under § 514.105(b) of this chapter.

(3) A "Type C medicated feed" is intended as the complete feed for the animal or may be fed top dressed on or offered free-choice in conjunction with other animal feed. It contains a substantial quantity of nutrients

including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 50 percent of the weight of the Type A medicated article. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Type A medicated article requires an application approved under § 514.105(b) of this chapter.

(4) New animal drugs for use in animal feed are placed in three categories as follows:

(i) *Category I*—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) *Category II*—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved.

(iii) *Category III*—These drugs are regulated on a "no-residue" basis or with a "zero" tolerance because of a carcinogenic concern.

b. By revising § 558.4, to read as follows:

§ 558.4 Medicated feed applications.

(a) Section 512(a)(1) of the act provides that a new animal drug intended for use in the manufacture of an animal feed shall be deemed to be unsafe for such purposes, unless the consignee for the drug holds an approved medicated feed application. Therefore, the manufacture of all medicated feeds, including those provided for in §§ 510.515, 558.15, and 558.20 directly from Type A medicated articles, are required to be the subject of approved medicated feed applications unless exempted under § 558.4(b).

(b) Exemptions from the requirement of an approved medicated feed application for the manufacture of Type B and Type C medicated feeds are based upon the public health significance of the drug. Animal drugs for use in animal feeds are identified in Categories I through III with the categories in order of increased public health significance. An approved medicated feed application is not required for the manufacture of any medicated animal feed produced from a Type B or Type C medicated feed conforming to the conditions for use prescribed by regulation.

(c) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type B and Type C medicated feeds, as follows:

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Category I.

Drug	Type B Maximum (200 X)	Assay Limits (% of Labeled Amount) Type B	Type C
Aklomide	22.75 g/lb (5.0%)	90-110	85-120
Ammonium chloride	8.0 - 16.5 oz/lb	90-110	85-120
Amprolium with or without Ethopabate	22.7 g/lb (5.0%)	94-114	85-115
Bacitracin (from bacitracin methylene disalicylate or zinc bacitracin)	10.0 g/lb	85-115	70-130
Bambermycins	800 g/ton	90-110	70-130
Buquinolate	9.8 g/lb (2.2%)	90-110	85-120
Chlortetracycline	10 g/lb	95-125	70-130
Coumaphos	90.8 g/lb (20%)	95-115	80-120
Decoquinate	2.72 g/lb (0.6%)	90-105	80-120
Dichlorvos	5.0 g/lb (11.0%)	100-115	80-130
Erythromycin (thiocyanate salt)	6.47 g/lb	85-115	<20 g/ton 50-150 >20 g/ton 75-125
Ethylenediamine dihydriodide	337.5 g/ton (0.037%)	90-110	85-115
Iodinated casein	20 g/lb (4.4%)	85-115	75-125
Nequinate	1.83 g/lb (0.4%)	95-112	80-120
Nystatin	5.0 g/lb	85-115	75-125
Oleandomycin	1.125 g/lb	85-120	70-130
Oxytetracycline	10.0 g/lb	90-120	65-135
Penicillin	10.0 g/lb	80-120	65-135
Penicillin, Streptomycin	1.5 g/lb 7.5 g/lb	80-120 85-115	65-135 70-130
Poloxalene	12.0%	90-110	85-115
Tylosin	10.0 g/lb	80-120	75-125
Virginiamycin	5.0 g/lb	85-115	70-130
Zoalene	11.4 g/lb (2.5%)	98-104	85-115

Category II.

Drug	Type B Maximum (100 X)	Assay Limits (% of Labeled Amount) Type B	Type C
Arsanilate Sodium	4.5 g/lb (1.0%)	98-108	75-125
Arsanilic acid	4.5 g/lb (1.0%)	98-108	75-125
Butynorate	17.0 g/lb (3.75%)	90-110	85-115
Butynorate, Sulfanitran, Dinsed, Roxarsone	9.05 g/lb (2.0%) 13.6 g/lb (3.0%) 9.05 g/lb (2.0%) 2.27 g/lb (0.5%)	90-110 85-115 90-110 95-103	85-115 75-125 85-115 85-120
Butynorate, Piperazine, Phenothiazine	63.45 g/lb (14.0%) 49.85 g/lb (11.0%) 272.9 g/lb (58.0%)	90-110 90-110 90-110	85-115 85-115 85-115
Carbarsone	17 g/lb (3.75%)	93-102	85-115
Clopidol	5.7 g/lb (1.25%)	94-106	80-120
Famphur	5.5 g/lb	100-110	90-115
Hygromycin B	1200 g/ton	90-110	75-125
Lasalocid	5.65 g/ton (1.25%)	100-120	75-125
Levamisole	36 g/lb	85-120	85-125
Lincomycin	2.0 g/lb	90-115	80-130
Monensin	5.5 g/lb	90-110	75-125
Neomycin	7.0 g/lb	80-120	70-125
Neomycin, Oxytetracycline	7.0 g/lb 10.0 g/lb	80-120 80-120	70-125 65-135
Nicarbazine	5.675 g/lb (1.25%)	98-106	80-120
Nitarsone	8.5 g/lb (1.875%)	90-110	85-115
Novobiocin	17.5 g/lb	85-115	80-120
Phenothiazine	66.5 g/lb	90-110	85-115
Piperazine	165 g/lb (40.25%)	90-110	85-115
Pyrantel tartrate	4.8 g/lb	90-110	85-115
Robenidine	1.5 g/lb (0.33%)	95-115	80-120
Ronnel	6.0%	85-115	80-120
Roxarsone	2.275 g/lb (0.5%)	95-103	85-120
Roxarsone, Aklomide	2.275 g/lb (0.5%) 11.35 g/lb (2.5%)	95-103 90-110	85-120 85-120

Category II.

Drug	Type B Maximum (100 X)	Assay Limits (% of Labeled Amount) Type B	Type C
Roxarsone, Clopidol, Bacitracin methylene disalicylate	2.275 g/lb (0.5%) 11.35 g/lb (2.5%) 5 g/lb	95-103 94-106 85-115	85-120 80-120 70-130
Roxarsone, Monensin	2.275 g/lb (0.5%) 5.5 g/lb	95-103 90-110	85-120 75-125
Sulfadimethoxine with Ormetoprim	5.65 g/lb (1.25%)	95-115	75-125
Sulfaethoxypyridazine	11.0%	95-105	85-115
Sulfamerazine	4.0%	85-115	80-120
Sulfamethazine	5.0 g/lb (1.25%)	85-115	80-120
Sulfamethazine, Chlortetracycline, Penicillin	5.0 g/lb (1.25%) 5.0 g/lb 2.5 g/lb	85-115 95-125 80-120	80-120 70-130 65-135
Sulfamethazine, Chlortetracycline	5 g/lb (1.25%) 5.0 g/lb	85-115 95-125	80-120 70-130
Sulfamethazine, Tylosin	5 g/lb (1.25%) 5 g/lb	85-115 80-120	80-120 75-125
Sulfanitran, Aklomide	13.6 g/lb (3.0%) 11.29 g/lb (2.5%)	85-115 90-110	75-125 85-120
Sulfanitran, Aklomide, Roxarsone	13.6 g/lb (3.0%) 11.2 g/lb (2.5%) 2.715 g/lb (0.625%)	85-115 90-110 95-103	75-125 85-125 70-130
Sulfanitran, Aklomide, Roxarsone	13.6 g/lb (3.0%) 11.2 g/lb (2.5%) 2.27 g/lb (0.5%)	85-115 90-110 95-103	75-125 85-120 80-120
Sulfaquinoxaline	11.2 g/lb (2.5%)	85-115	80-120
Sulfathiazole, Chlortetracycline, Penicillin	5 g/lb (1.25%) 5 g/lb 2.5 g/lb	85-115 85-125 80-120	80-120 70-130 65-135
Thiabendazole	45.4 g/lb (10.0%)	94-106	85-115

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Category III.

Drug	Type B Maximum (50 X)	Assay Limits (% of Labeled Amount) Type B	Type C
Carbadox	1.25 g/lb (0.0875%)	90-110	75-125
Chlormadinone acetate	0.011%	85-115	75-125
Dimetridazole	4.4 g/lb (1.0%)	96-103	85-120
Furazolidone	5 g/lb (1.1%)	95-105	85-115
Ipronidazole	1.414 g/ton (0.313%)	98-115	75-125
Melengestrol acetate	0.011%	90-110	70-120
Nitrofurazone	5.0 g/lb (1.0%)	90-110	80-120
Nitromide,	5.67 g/lb (1.25%)	90-110	85-115
Sulfanitran	6.8 g/lb (0.625%)	85-115	75-125
Nitromide,	5.67 g/lb (1.25%)	90-110	85-115
Sulfanitran,	6.8 g/lb (0.625%)	85-115	75-125
Roxarsone	1.135 g/lb (0.25%)	95-103	85-120

(d) When drugs from more than one category are in combination, the category defining the most restricted use will apply to the combination drug product.

c. In § 558.15 by revising the introductory text of paragraph (g) and paragraph (g)(2), to read as follows:

§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

* * * * *

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from another Type A medicated article that is in compliance with the requirements of this section.

* * * * *

(2) The following is a list of drug combinations permitted when prepared from Type A medicated articles listed in paragraph (g)(1) of this section. Drug combinations listed in Subpart B of this part name their sponsors and are incorporated herein by reference because they are safe and effective by contemporary standards, or such sponsors have been notified of any additional safety or efficacy data required on an individual basis:

* * * * *

d. By adding new § 558.20, to read as follows:

§ 558.20 Drugs used in medicated feeds in use before January 1, 1958 which are not otherwise listed; interim listing.

Applications for animal feeds bearing or containing new animal drugs must contain a reference to a section in the new animal drug regulations where the drug and the intended use is listed. For the purposes of such applications the following list of drugs was compiled. The list identifies drugs which must be the subject of approved medicated feed applications and which are not listed for the indicated uses in other new animal drug regulations. The drugs are not listed elsewhere since they were in use prior to the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act of January 1, 1958, which amendment required the listing of such drugs in appropriate regulations.

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Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Arsanilate sodium	Swine	0.005-0.01%	Increase rate of gain and improve feed efficiency in growing swine.	Withdraw 5 days before slaughter. As sole source of organic arsenic.
Arsanilate sodium	do	0.01%	Control of swine dysentery (hemorrhagic enteritis, bloody dysentery).	Withdraw 5 days before slaughter. Feed continuously as sole source of organic arsenic.
Arsanilate sodium	do	0.025-0.04%	Treatment of swine dysentery (hemorrhagic enteritis, bloody dysentery).	Withdraw 5 days before slaughter. Feed for 5-6 days as sole source of organic arsenic.
Arsanilic acid	Swine	0.005-0.01%	Increase rate of gain and improve feed efficiency in growing swine.	Withdraw 5 days before slaughter. As sole source of organic arsenic.
Arsanilic acid	do	0.01%	Control of swine dysentery (hemorrhagic enteritis, bloody dysentery).	Withdraw 5 days before slaughter. Feed continuously as sole source of organic arsenic.
Arsanilic acid	do	0.025-0.04%	Treatment of swine dysentery (hemorrhagic enteritis, bloody dysentery).	Withdraw 5 days before slaughter. Feed for 5-6 days as sole source of organic arsenic.
Butynorate (dibutyltin dilaurate)	Turkeys	0.0375%	As an aid in the prevention of coccidiosis (caused by E. meleagridis, E. meleagrimitis, E. gallopavonis) and hexamitiasis.	Withdraw 7 days before slaughter.

Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Butynorate plus sulfanitran, dinsed and roxarsone	do	0.02% 0.03% 0.02% 0.0025- 0.005%	Aid in stimulating growth and improving feed efficiency; preventing coccidiosis (E. meleagridis, E. meleagrimitis, E. gallopavonis), large roundworms, tapeworms and hexamitiasis.	do
Ethylenediamine dihydriodide	Chickens and Turkeys	1/4 lb/ton	An aid in the removal of mucus from upper respiratory tract following treatment for chronic respiratory disease (air-sac	Treat birds with caution until tolerance is determined, because of variation in susceptibility to iodides. Treat 5-7 days.
Ethylenediamine dihydriodide	Swine	250 to 500 mg daily.	By loosening mucus and congestion, aid in control of respiratory difficulties. Aids in loosening mucus in upper respiratory tract.	Treat animals with caution until tolerance is determined because of variation in susceptibility to iodides. Treat for 7 days.
Ethylenediamine dihydriodide	Sheep	Self feed at rate to provide 12 mg per head per day.	As an aid in prevention of soft tissue lumpy jaw in sheep.	

Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Ethylenediamine dihydriodide	Cattle	400 to 500 mg per head daily.	Aids in the treatment of foot rot caused by Spnerophorus necrophorus; aids in treatment of soft tissue lumpy jaw caused by Actinobacillus lignierisi.	Treat animals with caution until tolerance is determined, because of variation in susceptibility to iodides. Not to be administered to dairy cattle in production. Feed for 2-3 weeks.
Ethylenediamine dihydriodide	Cattle	50 mg per head daily in feed continuously.	Aids in the prevention of foot rot and soft tisssue lumpy jaw.	
Neomycin sulfate	Chickens, Turkeys and Ducks	70-140 g/ton of complete feed as neomycin base.	For treatment of bacterial enteritis (nonspecific enteritis, salmonellosis, bluecomb, mud fever).	
Neomycin sulfate	Mink	140 g/ton of complete feed as neomycin base.	For treatment of bacterial enteritis and diarrhea.	
Neomycin sulfate	Swine, Calves, Cattle, Horses, Sheep, Goats	70-140 g/ton of complete feed as neomycin base.	For treatment of bacterial enteritis (scours, diarrhea, bloody dysentery, vibrionic dysentery, winter dysentery, white scours, colibacillosis, salmonellosis; diarrhea caused by E. coli, vibrio and salmonella organisms); enterotoxemia in lambs.	

Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Nitarsone (4-nitrophenyl-arsonic acid)	Chickens and Turkeys	0.01875%	As an aid in the prevention of blackhead.	Withdraw 5 days before slaughter. As sole source of organic arsenic.
Phenothiazine	Chickens	0.5 g per bird.	Removal of cecal worms (Herterakis gallinarum).	For 1 day only.
Phenothiazine	Turkeys	1 g per bird.	do	do.
Phenothiazine	Swine	5 g up to 25 lb; 8 g, 26-50 lb; 10 g, 51-100 lb; 20 g, 101-200 lb; 30 g, 201 lb and up.	Removes nodular worms (Oesophagostomum).	
Phenothiazine	Sheep and Goats	25-60 lb body weight, 12.5 g; over 60 lb body weight, 25 g.	Removal of stomach worms (Haemonchus, Ostertagia, and Trichostrongylus spp.); large-mouth bowel worms (Chabertia spp.), and hookworms (Bunostomum spp.).	Milk from dairy animals which have been treated with phenothiazine should not be used for food for four days following treatment.
Phenothiazine	do	1 g/head/day	Control of stomach worms (Haemonchus, Ostertagia, and Trichostrongylus spp.); large-mouth bowel worms and hookworms (Chabertia spp.), (Bunostomum spp.).	Do not feed to lactating dairy animals. Feed continuously.
Phenothiazine	Cattle	10 g/100 lb body weight, up to a maximum of 70 g.	Removes common stomach worms (Haemonchus), lesser stomach worms (Ostertagia), hair worms, bankrupt worms (Trichostrongylus spp.).	Milk from dairy animals which have been treated with phenothiazine should not be used for food for four days following

Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
			nodular worm (Oesophagostomum spp.), and large-mouth bowel worms (Chabertia spp.).	treatment.
Phenothiazine	do	20 g/100 lb body weight up to a maximum of 80 g. Micronized (2-3 micron size particles)--(10 g/100 lb body weight, up to a maximum of 60 g.	Hookworms (Bunostomum spp.)	For 1 day only. Milk from dairy animals which have been treated with phenothiazine should not be used for food for four days following treatment.
Phenothiazine	Cattle	0.25 g/100 lb body weight/day. For adult average dose is 2 g.	Controls common stomach worms (Haemonchus), lesser stomach worms (Ostertagia), hair worms, bankrupt worms (Trichostrongylus spp.), nodular worm (Oesophagostomum spp.) and large-mouth bowel worms (Chabertia spp.).	Do not feed to lactating dairy animals.
Phenothiazine	Horses and Mules	2.5 g/100 lb body weight up to a maximum of 30 g.	Removal of strongyles (Strongylus spp.).	For 1 day only.

Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Phenothiazine	do	2 g per head per day.	do	For continuous use; feed 2 g per head per day for 21 consecutive days then none for 9 days. Repeat the feeding schedule as long as worm control is desired.
Piperazine	Chickens (under 6 weeks of age)	0.2-0.4%	Control of infestation of large roundworms (Ascaris).	As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 50 mg of piperazine per bird.
Piperazine	Chickens (over 6 weeks of age)	0.2-0.4%	Control of infestation of large roundworms (Ascaris).	As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100 mg of piperazine per bird.
Piperazine	Turkeys (under 12 weeks of age)	0.2-0.4%	Control of infestation of large roundworms (Ascaris).	As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100 mg of piperazine per bird.

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Drug Ingredient	Species	Use Levels	Indications for Use	Limitations
Piperazine	Turkeys (over 12 weeks of age)	0.2-0.4%	do	As sole source of feed. For 1 day treatment. Directions for use should assure that the amount of feed consumed will furnish in 1 day 100-400 mg of piperazine per bird according to size.

e. By republishing Subpart B of Part 558 to reflect the proposed definitions and other considerations, as follows:

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

Sec.
558.35 Aklomide.
558.45 Ammonium chloride, feed grade.
558.55 Amprolium.
558.58 Amprolium and ethopabate.
558.60 Arsanilate sodium.
558.62 Arsanilic acid.
558.76 Bacitracin methylene disalicylate.
558.78 Bacitracin zinc.
558.95 Bambermycins.
558.105 Buquinolate.
558.115 Carbadox.
558.120 Carbarsone (not U.S.P.).
558.126 Chlormadinone acetate.
558.128 Chlortetracycline.
558.145 Chlortetracycline, penicillin procaine, and sulfamethazine.
558.155 Chlortetracycline, penicillin procaine, and sulfathiazole.
558.175 Clopidol.
558.185 Coumaphos.
558.195 Decoquinate.
558.205 Dichlorvos.
558.240 Dimetridazole.
558.248 Erythromycin thiocyanate.
558.254 Famphur.
558.262 Furazolidone.
558.266 Griseofulvin.
558.274 Hygromycin B.
558.295 Iodinated casein.
558.305 Iponidazole.
558.311 Lasalocid sodium.
558.315 Levamisole hydrochloride (equivalent).
558.325 Lincomycin.
558.342 Melengestrol acetate.
558.355 Monensin.
558.365 Nequinate.
558.366 Nicarbazin.
558.367 Niclosamide.
558.370 Nitroforazone.
558.376 Nitromide and sulfanitran.
558.415 Novobiocin.
558.430 Nystatin.
558.435 Oleandomycin.
558.450 Oxytetracycline.
558.460 Penicillin.
558.464 Poloxalene.
558.465 Poloxalene liquid Type C medicated feed article.
558.485 Pyrantel tartrate.
558.515 Robenidine hydrochloride.
558.525 Ronnel.
558.526 Ronnel liquid Type C medicated feed.
558.530 Roxarsone.
558.565 Styrylpyridinum chloride, diethylcarbamazine (as base).
558.575 Sulfadimethoxine, or metoprim.
558.579 Sulfaethoxypyridazine.
558.582 Sulfamerazine.
558.615 Thiabendazole.
558.625 Tylosin.
558.630 Tylosin and sulfamethazine.
558.635 Virginiamycin.
558.680 Zoalene.

§ 558.35 Aklomide.

(a) [Reserved]
(b) [Reserved]
(c) *Approvals.* Type A medicated article to 017210 in § 510.600(c) of this chapter, as follows:
(1) 50 percent aklomide.
(2) 25 percent aklomide and 20 percent sulfanitran.
(3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.
(4) 50 percent aklomide and 10 percent roxarsone.
(d) [Reserved]
(e) [Reserved]
(f) *Related tolerances.* See § 556.30 of this chapter.
(g) *Conditions of use.* It is used for chickens as follows:
(1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).
(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix.*
(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption.
(2) *Amount per ton.* Aklomide, 227 grams (0.025 percent) with sulfanitran, 181.6 grams (0.02 percent).
(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*
(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter.
(3) *Amount per ton.* Aklomide, 227 grams (0.025 percent) with sulfanitran, 181.6 grams (0.02 percent) and roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).
(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina;*

growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(4) *Amount per ton.* Aklomide, 227 grams (0.025 percent) with roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella,* and *E. necatrix;* growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

§ 558.45 Ammonium chloride, feed grade.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated article: 99 percent to 011462 and 000018 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) [Reserved]

(f) *Conditions of use.* It is used for cattle and sheep as follows:

(1) *Amount per day.* 21.3–35.5 grams (0.75–1.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For range cattle.

(2) *Amount per day.* 28.4–42.5 grams (1.0–1.5 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For fattening cattle.

(3) *Amount per day.* 7.1 grams (0.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For sheep.

§ 558.55 Amprolium.

(a) *Approvals.* (1) Type A medicated feed article: 25 percent to No. 000006 in § 510.600(c) of this chapter for use as in paragraph (e)(1) of this section.

(2) [Reserved]

(b) [Reserved]

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances.* See § 556.50 of this chapter.

(e) *Conditions of use*—(1) *Calves.* It is used as follows:

(*i*) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer form Type C medicated feeds/containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(*ii*) *Amount.* 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

(*ii*) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer from a Type C medicated feed article containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium.

(2) *Chickens and turkeys.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(f) 36.3 to 113.5 (0.004% to 0.0125%)..	.....	Replacement chickens; development of active immunity to coccidiosis..	Feed as follows—	

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium grams per ton	*Amprolium grams per ton*	*Amprolium grams per ton*
Severe exposure coccidiosis..	113.5 (0.0125%).....	72.6–113.5 (0.008%–0.0125%).	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis..	72.6–113.5 (0.008%–0.0125%).....	54.5–113.5 (0.006%–0.0125%).	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis..	36.3–113.5 (0.004%–0.0125%).....	36.3–113.5 (0.004%–0.0125%).	36.3–113.5 (0.004%–0.0125%)

Arsanilate sodium 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).
Arsanilic acid 90 (0.01%)	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).
Arsanilic acid 90 (0.0%) plus erythromycin 4.6 to 16.5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).
Arsanilic acid 90 (0.01%) plus erythromycin 92 5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).
	2. Replacement chickens; development of active immunity to coccidiosis; growth promotion arid feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 5 d before slaughter, as sole source of organic arsenic. Feed according to subtable in item (i).
Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
			Amprolium grams per ton	*Amprolium grams per ton*	*Amprolium grams per ton*
	Bacitracin 100 to 200	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).		As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).	
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.		Not to be fed to laying chickens; as chlortetracycline hydrochloride. Feed according to subtable in item (i).	
(i) 36.3 to 113.5 (0.004% to 0.0125%).	Erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.		As erythromycin thiocyanate. Feed according to subtable in item (i)	
	Erythromycin 92.5	1. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of infectious coryza.		Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
		2. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress..		Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
	Erythromycin 185	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.		Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).	
	Hygromycin B 8 to 12	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).		Feed according to subtable in item (i)	
	Penicillin 2.4 to 50	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.		As penicillin. Feed according to subtable in item (i)	
	Penicillin plus streptomycin 90 to 180 (of combination).	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		Type C medicated feed contains 16.7% penicillin; as penicillin procaine, as streptomycin sulfate. Feed according to subtable in item (i).	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion, and feed efficiency; improving pigmentation.		Withdraw 5 d before slaughter; as sole source of organic arsonic. Feed according to subtable in item (i).	
(ii) 72.6 to 113.5 (0.008% to 0.0125%)..		Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella* only..		Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (ii).	
	Arsanilate sodium 90 (0.01%).	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.		Withdraw 5 d before slaughter, as sole source of organic arsenic	
	Arsanilic acid 90 (0.01%.	do		do	
	Bacitracin 100 to 200	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).		As bacitracin methylene disalicylate, or bacitracin zinc	
	Chlortetracycline 100 to 200.	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.		Not for laying chickens; as chlortetracycline hydrochloride	
	Hygromycin B 8 to 12	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella* only; control of infestation of large round worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).		Feed according to subtable in item (ii)	
	Penicillin 2.4 to 50	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency.		As penicillin procaine	
	Penicillin plus streptomycin 90 to 180 (of combination).	Treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		Type C medicated feed contains 16.7% penicillin; as penicillin procaine; as streptomycin sulfate.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.		Withdraw 5 d before slaughter; as sole source of organic arsenic	
(iii) 113.5 (0.0125%)..		1. Laying chickens; prevention of coccidiosis			
		2. Laying chickens; treatment of coccidiosis			For moderate outbreaks of coccidiosis, administer for 2 weeks
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain; improved feed efficiency, and improved pigmentation.			Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; roxarsone as provided by 017210 in § 510.600(c) of this chapter, bambermycins by 012799; withdraw 5 d before slaughter.
(iv) 113.5 to 227 (0.0125% to 0.025%).	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.			
		2. Turkeys; prevention of coccidiosis			
	Arsanilate sodium 90 (0.01%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.			Withdraw 5 d before slaughter; as sole source of organic arsenic
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.			do
	Arsanilic acid 90 (0.01%)	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.			do
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.			do
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.			Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.

Amprolium in grams per ton	Combination in grams per ton	Indications for use		Limitations		Sponsor
		Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age	
			Amprolium grams per ton	*Amprolium grams per ton*	*Amprolium grams per ton*	
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.		Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.		
(iv) 113.5 to 227 (0.0125% to 0.025%).	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory diseases.		Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.		
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.		Withdraw 5 d before slaughter; as sole source of organic arsenic		
	Bacitracin 4 to 50	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.		As bacitracin methylene disalicylate or bacitracin zinc; bacitracin zinc by 012769, 046573 in § 510.600(c) of this chapter.		
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.		do		
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		do		
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		As bacitracin zinc		
	Bacitracin 100 to 500	Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever).		As bacitracin zinc		
	Bacitracin plus penicillin 100 to 500 (of combination).	do		Type C medicated feed contains 50% to 75% of bacitracin but not more than 126 g penicillin; as penicillin procaine, as bacitracin zinc.		
	Chlortetracycline 100 to 200.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.		Not for laying chickens, as chlortetracycline hydrochloride		
	Erythromycin 4.6 to 18.5	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.		As erythromycin thiocyanate		
(iv) 113.5 to 227 (0.0125% to 0.025%)	Erythromycin 92.5	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.		Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.		
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.		Feed for 7 to 14 d; withdraw 24 h before slaughter		
	Erythromycin 185	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.		Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.		
	Hygromycin B 8 to 12	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms (*Heterakis gallinae*) and capillary worms, *Capillaria obsignata*.		Feed according to subtable in item(i)		
	Penicillin 2.4 to 50	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.		As penicillin procaine		
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.		do		
	Penicillin plus streptomycin 90 to 180 (of combination).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		Type C medicated feed contains 16.7% penicillin; as penicillin procaine; as streptomycin sulfate.		
		2. Turkeys, prevention of coccidiosis, treatment of infectious sinusitis, blue comb (mud fever), hexamitiasis.		Type C medicated feed contains not less than 2.4 g of penicillin nor less than 12 g of streptomycin; as penicillin procaine; as streptomycin sulfate.		
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%)	1. Broiler chickens and replacement chickens were immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.		Withdraw 5 d before slaughter, as sole source of organic arsenic		
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency improving pigmentation.		do		
(v) 227 (0.025%)		Laying chickens; treatment of coccidiosis		For severe outbreaks of coccidiosis; administer for 2 weeks		

§ 558.58 Amprolium and ethopabate.

(a) *Approvals.* Type A medicated article: 25 percent amprolium and 0.8 percent ethopabate; 25 percent amprolium and 8 percent ethopabate; 5 percent amprolium and 0.16 percent ethopabate; 5 percent amprolium and 1.6 percent ethopabate; to 000006 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances.* See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use.* (1) It is used for chickens as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.....	Not for laying hens; as sole source of amprolium.....	
(ii) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025 to 0.00375 pct)	Broiler chickens; as an aid in the prevention of coccidiosis, for increased rate of weight gain improved feed efficiency, and pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic, amprolium and ethopabate as provided by 000006 in sec. 510.600(c) of this chapter, roxarsone by 017210, bambermycins by 000039; withdraw 5 d before slaughter.	
	Lincomycin 2 to 4	Broiler chickens; for increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis.	NOt for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	
	Lincomycin 2 to 4 plus roxarsone 45.4 (0 005 pct).	Broiler chickens; for increase in rate of weight gain; improved feed efficiency and; pigmentation; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, for increased rate of weight gain in broiler chickens raised in floor pens..	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by 017210 in sec. 510.600(c) of this chapter; combinations as provided by 000006.	
(iii) Amprolium 113.5 (0.0125 pct) and ethopabate 36.3 (0.004 pct).	.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina E. maxima* and *E. brunetti* is likely to occur.	Not for chickens over 16 weeks of age.....	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improve pigmentation.	Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thiocyanate.	
	Bacitracin 4 to 50	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by 046573 or bacitracin zinc as provided by 012769 in sec. 510.600(c) of this chapter feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by 000006 in sec. 510.600(c) of this chapter.	
	Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017 pct to 0.005 pct).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter, as sole source of amprolium and organic arsenic, do not use as a treatment for outbreaks of coccidiosis feed as the sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard, amprolium and ethopabate as provided by 000006 in sec. 510.600(c) of this chapter, bacitracin zinc as provided by 012769; roxarsone as provided by 017210, combination as provided by 012769.	012769
	Bacitracin 10 plus roxarsone 30 to 45.4 (0.0033 pct to 0.005 pct).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, improved feed efficiency and improved pigmentation.	....do.....	012769
	Bambermycins 1 to 3	Broiler chickens; as an aid in the prevention of coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, for increased rate of weight gain, and improved feed efficiency.	Feed continuously as the sole ration as sole source of amprolium, amprolium and ethopabate as provided by 000006 in sec. 510.600(e) of this chapter, bambermycins as provided by 012799.	
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025 pct to 0.00375 pct).	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, for increased rate of weight gain; improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as source of amprolium and organic arsenic amprolium and ethopabate as provided by 000006 in sec. 510.600(c) of this chapter; roxarsone by 017210; bambermycins by 012799. Withdraw 5 d before slaughter.	
	Erythromycin 4.6 to 18.5	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	Not for laying hens; withdraw 24 h before slaughter; as erythromycin thiocyanate.	
(iv) Amprolium 113.5 to 227 (0.0125 to 0.025 pct) and ethopabate 3.6 (0.0004 pct).	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired, prevention of coccidiosis.	Not for laying hens.....	
	Arsanilic acid 90 (0.01 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired, prevention of coccidiosis; growth promotion and feed efficiency improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress; and 3 to 6 d after stress, withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	Feed for 7 to 14 d; withdraw 5 h before slaughter; as sole source of organic arsenic; not for laying hens.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 135.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired, prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate; not for laying hens	
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	do	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As bacitracin zinc not for laying hens	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As bacitracin methylene disalicylate; not for laying hens; as sole source of organic arsenic; withdraw 5 d before slaughter.	
	Chlortetracycline 100 to 200.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis), prevention of synovitis.	Not for laying hens; as chlortetracycline hydrochloride	
	Chlortetracycline 200	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chlortetracycline.	In low calcium Type medicated feeds containing 0.8 pct dietary calcium and 1.5 pct sodium sulfate; feed continously as sole ration for not more than the 1st 3 weeks of life; not for laying hens.	
	Erythromycin 92.5	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.	
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed to 7 to 14 d; withdraw 24 before slaughter; not for laying hens	
	Erythromycin 185	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Penicillin 2.4 to 50	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Not for laying hens; as penicillin procaine	
	Penicillin plus streptomycin 90 to 180 (of combination).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type C medicated feed contains 16.7 pct penicillin; as penicillin procaine; as streptomycin sulfate; not for laying hens.	
	Roxarsone 22.7 to 45.5 (0.0025 to 0.005 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
(v) Amprolium 136.2 (0.015 pct) and ethopabate 3.6 (0.0004 pct).	Bacitracin 10	Broiler chickens, as an aid in the prevention of coccidiosis; growth promotion and feed efficiency.	Feed as sole ration; use as sole source of amprolium; do not feed to laying hens; as bacitracin methylene disalicylate.	047019

§ 558.60 Arsanilate sodium.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated article: 20, 50, or 100 percent arsanilate sodium, to 043731 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.680 of this chapter.

(e) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

(i) *Grams per ton.* 90 (0.01 percent).

(ii) *Indications for use.* For growth promotion and feed efficiency; improving pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Arsanilate sodium may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Zoalene as in § 558.60.

§ 558.62 Arsanilic acid.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated article: 20, 50, or 100 percent arsanilate acid to 043731 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) Conditions of use—(1) It is used for chickens and turkeys as follows:

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
90 (0.01 pct)		1. Chickens; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic	
		2. Turkeys; growth promotion and feed efficiency; improving pigmentation.	do	
	Erythromycin 4.6 to 18.5	Chickens; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Erythromycin 92.5	1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.	
		2. Chickens; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Erthromycin 185	Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	

(2) Arsanilic acid may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Bacitracin zinc as in § 558.78.

(iv) Bacitracin and zoalene as in § 558.680.

(v) Buzuinolate as in § 558.105.

(vi) Zoalene as in § 558.680.

§ 558.76 Bacitracin methylene disalicylate.

(a) *Approvals.* Type A medicated article: 25, 40, or 50 percent bacitracin methylene disalicylate to 046573 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(d) *Related tolerances.* See § 556.70 of this chapter.

(e) *Conditions of use.* (1) It is used as follows:

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50		Chickens, turkeys, and pheasants; growth promotion and feed efficiency.		
(ii) 5 to 20		Quail; not over 5 weeks of age; growth promotion and feed efficiency.		
(iii) 10 to 50		1. Swine; growth promotion and feed efficiency		
		2. Chickens; maintaining or increasing egg production	Feed 50 g per ton 1st 4 to 8 weeks of egg production; 10 to 50 g per ton for remainder of egg-laying period.	
(iv) 50 to 100		1. Chickens; prevention of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).		
		2. Swine; aid in prevention of bacterial swine enteritis		
		3. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		
(v) 100		1. Chickens; maintaining or increasing hatchability of eggs		
		2. Chickens; during times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.		
		3. Chickens; prevention of early mortality of chicks due to susceptible organisms.	For chicks, in starter ration	
		4. Swine; treatment of bacterial swine enteritis		
100 of combination	Penicillin	1. Chickens; maintaining or increasing hatchability of eggs	Type C medicated feed combination containing 75 g of bacitracin plus 25 g of penicillin; as penicillin procaine	
		2. Swine; treatment of bacterial swine enteritis	Type C medicated feed containing 50 to 75 pct of bacitracin; as penicillin procaine.	
(vi) 100 to 200		1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).		
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		
100 to 200 of combination.	Penicillin	1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).	Type C medicated feed containing not less than 25 g of penicillin nor less than 50 g of bacitracin; as penicillin procaine.	
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).	do	

(2) It is used for cattle as follows:

(i) *Amount.* 70 milligrams per head per day.

(*a*) *Indications for use.* Feedlot beef cattle: reduction in the number of liver condemnations due to abscesses.

(*b*) *Limitations.* Administer continuously throughout the feeding period.

(ii) *Amount.* 250 milligrams per head per day.

(*a*) *Indications for use.* Feedlot beef cattle: reduction in the number of liver condemnations due to abscesses.

(*b*) *Limitations.* Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) It is also used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium with ethopabate as in § 558.58.

(iii) Arsanilic acid with zoalene as in § 558.680.

(iv) Carbarsone (not U.S.P.) as in § 558.120.

(v) [Reserved]

(vi) Hygromycin B as in § 558.274.

(vii) Monensin as in § 558.355.

(viii) Lasalocid sodium as in § 558.311.

(ix) Monensin and roxarsone as in § 558.355.

§ 558.78 Bacitracin zinc.

(a) *Approvals.* (1) Premix level of 50 grams bacitracin zinc per pound to 046573 in § 510.600(c) of this chapter for use as in paragraph (e)(1)(i) and (ii) only of this section.

(2) Premix levels of 10, 25, 40, and 50 grams of bacitracin zinc per pound to 012769 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(b) [Reserved]

(c) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(d) *Related tolerances.* See § 556.70 of this chapter.

(e) *Conditions of use.* (1) It is used in complete feeds as follows:

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50		1. Chickens, turkeys, and pheasants; growth promotion and feed efficiency.		
		2. Chickens, turkeys and phesants; for increased rate of weight gain and improved feed efficiency.	Growing chickens, turkeys, and pheasants	046573, 012769
(ii) 5 to 20		1. Quail; growth promotion and feed efficiency	In quail not over 5 weeks of age	
		2. Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as the complete feed to starting quail through 5 weeks of age.	046573, 012769
(iii) 10 to 50		1. Swine; growth promotion and feed efficiency		
		2. Chickens; maintaining or increasing egg production	Feed 50 g per ton 1st 4 to 6 weeks of egg production; 10 to 50 g per ton for remainder of egg-laying period.	012769
		3. Swine; increased rate of weight gain and improved feed efficiency.		012769
(iv) 50 to 100		1. Chickens, prevention of chronic respiratory disease (arisac infection); blue comb (nonspecific infections enteritis).		012769
		2. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		012769
		3. Swine; aids in the prevention of bacterial swine enteritis		012769
(v) 100		1. Chickens; maintaining or increasing hatchability of eggs		012769
		2. Chickens; during times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.		012769
		3. Swine; treatment of bacterial swine enteritis		012769
100 of combination	Penicillin	Swine; treatment of bacterial swine enteritis	Feed containing 50% to 75% bacitracin; as procaine penicillin	
(vi) 100 to 500		1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).		012769
		2. Chickens; prevention of early mortality of chicks due to susceptible organisms.	For chicks, in starter feed	012679
		3. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		012679
100 to 500 of combination.	Penicillin	1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).	Feed containing not less than 50% nor more than 75% of bacitracin except that it contains not more than 125 g of penicillin; as procaine penicillian.	
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).	do	

(2) It is used in feed for growing cattle at 35 to 70 milligrams per head per day as follows:

(i) To aid in stimulating growth and improving feed efficiency.

(ii) For increased rate of weight gain and improved feed efficiency; see sponsor 012769.

(3) Bacitracin zinc is used in accordance with the provisions of this section in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium with ethopabate as in § 558.58.

(iii) Arsanilic acid and zoalene as in § 558.680.

(iv) [Reserved]

(v) Hygromycin B as in § 558.274.

(vi) Monensin as in § 558.355.

(vii) Zoalene as in § 558.680.

§ 558.95 Bambermycins.

(a) [Reserved]

(b) *Approvals.* (1) Type A medicated article: 2 and 10 grams of bambermycins activity per pound to 012799 in § 510.600(c) of this chapter for use as provided in paragraph (e)(1) and (e)(2) (i) and (ii) of this section.

(2) Type A medicated article: 0.4 gram of bambermycins activity per pound to 012799 for use as provided in paragraph (e)(2) of this section.

(c) [Reserved]

(d) [Reserved]

(e) *conditions of use*—(1) *Broiler chickens.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (0.125 percent) plus ethopabate, 36.3 grams (.004 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina, E. maxima,* and *E. brunetti* is likely to occur. For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium; amprolium and ethopabate

as provided by No. 000006 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 1,13.5 grams (.0125 percent) plus ethopabate, 36.3 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina, E. maxima,* and *E. brunetti* is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic: amprolium and ethopabate as provided by .000006 in § 510.600(c) of this chapter, roxarsone as provided by No. 017210 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(iv) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 3.63 grams (.0004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by 000006 in § 510.600(c) of this chapter, roxarsone as provided by No. 017210. Withdraw 5 days before slaughter.

(v) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium as provided by 000006 in § 510.600(c) of this chapter, roxarsone as provided by 017210. Withdraw 5 days before slaughter.

(vi) *Amount per ton.* Bambermycins, 1 gram plus monensin, 90 to 110 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as monensin sodium provided by 000986 in § 510.600(c) of this chapter; as bambermycins provided by 012799 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Bambermycins, 1 gram plus monensin, 90 to 100 grams plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent).

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 days before slaughter; as monensin sodium provided by 000986 in § 510.600(c) of this chapter; as bambermycins provided by 012799 as roxarsone provided by 017210.

(viii) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent).

(*a*) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; zoalene as provided by 025700 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; feed as sole source of organic arsenic; withdraw 5 days before slaughter, zoalene as provided by 025700, roxarsone as provided by 017210 in § 510.600(c) of this chapter.

(2) *Growing-finishing swine.* It is used as follows:

(i) *Amount per ton.* 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

(*a*) *Indications for use.* For increased rate of weight gain.

(*b*) *Limitations.* Feed continuously as sole ration.

§ 588.105 Buquinolate.

(a) [Reserved]

(b) *Approvals.* Type A medicated feed article: 16.5 and 22 percent to 000149 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(e) *Related tolerances.* See § 556.90 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus arsanilic acid, 90 grams (0.01 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iv) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin, 2.4–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as penicillin procaine.

(v) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus bacitracin, 4–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as bacitracin zinc or bacitracin methylene disalicylate.

(vi) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin plus bacitracin, 3.6–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E.*

brunetti, and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; not less than 0.6 gram of penicillin nor less than 3 grams of bacitracin; as procaine penicillin plus bacitracin zinc or bacitracin methylene disalicylate.

(vii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus chlortetracycline, 200 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis); prevention of synovitis.

(*b*) *Limitations.* In low calcium type C medicated feeds containing 0.8 percent dietary calcium and 1 to 1.5 percent sodium sulfate; to be fed continuously for not more than the first 21 days of life.

(viii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus lincomycin, 2–4 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti, E. acervulina.*

(*b*) *Limitations.* For broiler and fryer chickens; feed continuously as the sole ration.

(ix) *Amount per ton.* Buquinolate, 75–100 grams (0.00825–0.011 percent) plus roxarsone, 22.7–34.0 grams (0.0025–0.00375 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; as sole course of organic arsenic; roxarsone as provided by 017210 in § 510.600(c) of this chapter.

(x) *Amount per ton.* Buquinolate, 100 grams (0.011 percent) plus bacitracin, 4–15 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* increased rate of weight gain.

(*b*) *Limitations.* Feed continuously as the sole ration; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xi) *Amount per ton.* Buquninolate, 100 grams (0.011 percent) combined with bacitracin, 19–35 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* For floor raised broiler or fryer chickens, feed continuously as sole ration; as bacitracin zinc provided by 012769 in § 510.600(c) of this chapter.

(2) *Broiler, fryer, roaster or replacement chickens*—(i) *Amount per ton.* 75–100 grams (0.00825–0.011 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed continuously as the sole ration; do not administer over 75 grams per ton (0.00825 percent) to replacement chickens over 20 weeks of age.

(3) *Laying or breeding chickens*—(i) *Amount per ton. 75 grams (0.00825 percent).*

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed to caged layers for 2 weeks following caging; feed continuously to layers and breeders kept on floors while in production or until marketed.

§ 558.115 Carbadox.

(a) [Reserved]

(b) *Approvals.* Type A medicated article: 2.2 percent (10 grams per pound) to 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.100 of this chapter.

(e) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(f) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in Type D medicated feed articles containing less than 15 percent crude protein.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increase rate of weight gain and improve feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in Type D medicated feed articles containing less than 15 percent crude protein.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106) percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severly debilitated animals; feed continuously as sole ration. Do not use in Type C medicated feeds containing less than 15 percent crude protein.

§ 558.120 Carbarsone (not U.S.P.).

(a) *Approvals.* (1) Type A medicated article: 37.5 percent carbarsone to 011794 in § 510.600(c) of this chapter.

(2) Type A medicated article: 25 percent carbarsone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 011794.

(b) [Reserved]

(c) [Reserved]

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use.* (1) It is used for turkeys as follows:

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(*a*) *Indications for use.* As an aid in the prevention of blackhead.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 10 grams per ton bacitracin (as bacitracin methylene disalicylate).

(*a*) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Carbarsone (not U.S.P.) may also be used in combination with:

(i) Zoalene as in § 558.680.

(ii) [Reserved]

§ 558.126 Chlormadinone acetate.

(a) *Approvals.* Type A medicated articles: 1 gm per lb. to 000986, 2 gm per lb. to 000033, in § 510.600(c) of this chapter.

(b) [Reserved]

(c) [Reserved]

(d) *Related tolerances.* See § 556.130 of this chapter.

(e) *Conditions of use.* It is used for beef heifers and beef cows as follows:

(1) *Amount.* 10 milligrams per head per day.

(2) *Indications for use.* Synchronization of estrus (heat).

(3) *Limitations.* Administer for 18 days; do not administer within 28 days of slaughter; do not administer to cows producing milk for food.

§ 558.128 Chlortetracycline.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated article: 10 and 50 gm per lb. Chlortetracycline to 010042 in § 510.600(c) of this chapter; 35 gm chlortetracycline with 7.7 percent (35 gm) sulfamethazine to 010042.

(d) *Related tolerances.* See § 556.150 of this chapter.

(e) *Conditions of use.* (1) It is used for cockatoos, macaws, and parrots as follows:

(i) *Amount.* 10 milligrams per gram of mash.

(ii) *Indications for use.* Treatment of psittacine birds suspected or known to be infected with psittacosis.

(iii) *Limitations.* As chlortetracycline hydrochloride.

(2) It is used for laboratory mice as follows:

(i) *Amount.* Not less than 100 grams per ton of feed.

(ii) *Indications for use.* As an aid in reducing the incidence of bacterial diarrhea.

(3) It is used as follows:

Table 1

Chlortetracycline in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 50		1. Chickens and turkeys; growth promotion and feed efficiency.	As chlortetracycline hydrochloride	
		2. Swine; growth promotion and feed efficiency	do	
(ii) 20 to 50		1. Lambs and growing sheep; growth promotion and feed efficiency.	do	
		2. Mink; growth promotion and feed efficiency; as an aid in increasing pelt size.	do	
(iii) 50 to 100		1. Chickens and turkeys; during times of stress, for prevention of diseases named in this section caused by organisms susceptible to the indicated levels of the cycline salt.	do	
		2. For chickens; prevention of chronic respiratory disease (air-sac infection).	do	
		3. For turkeys; prevention of infectious sinusitis, hexamitiasis	do	
		4. For laying chickens; maintaining or increasing egg production or hatchability of eggs.	do	
		5. For chicks; prevention of early mortality due to organisms susceptible to chlortetracycline.	do	
		6. Swine; maintenance of weight gain in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; preventon of bacterial swine enteritis; prevention of bacterial swine enteritis during times of stress.	do	
100 to 200		1. For chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride	
		2. For turkeys; treatment of blue comb (nonspecific infectious enteritis, mud fever), infectious sinusitis, hexamitiasis; prevention of synovitis.	As chlortetracyline hydrochloride	
		3. For chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracyline hydrochlonde as follows: In low-calcium, Type C medicated feed containing 0.8 pct dietary calcium, not to be fed continuously for more than 8 weeks; in low-calcium Type C medicated feed containing 0.40 to 0.55 pct dietary calcium, not to be fed continuously for more than 5 d; in low-calcium Type C medicated feed containing 0.8 pct dietary calcium and 1.to 1.5 pct sodium sulfate, to be fed continuously for not more than the 1st 3 weeks of life.	
		4. Swine; treatment of bacterial swine enteritis	As chlortetracyline hydrochloride	
(v) 200		1. For chickens; prevention and control of coccidiosis caused by *Eimeria necatrix* and *E. tenella*.	Not to be fed to laying chickens; as chlortetracyline hydrochloride in low-calcium Type C medicated feed containing 0.8 pct dietary calcium, not to be fed continuously for more than 8 weeks; in low-calcium Type C medicated feed containing 0.8 pct dietary calcium and 1.0 to 1.5 pct sodium sulfate, to be fed continuously for not more than the first 3 weeks of life.	
		2. For chickens; treatment of coccidiosis caused by *Eimeria necatrix* and *E. tenella*.	Not to be fed to laying chickens; as chlortetracyline hydrochloride in low-calcium Type C medicated feed containing 0.4 to 0.55 pct dietary calcium, not to be fed continuously for more than 5 d.	
		3. For chickens; control of synovitis	Not to be fed to laying chickens; as chlortetracyline hydrochlonde	
		4. For turkeys; control of snyovitis	As chlortetracyline hydrochloride	
		5. For broiler chickens; treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chlortetracyline.	In low-calcium Type C medicated feed containing 0.8 pct dietary calcium and 1.5 pct sodium sulfate; feed continuously as Type C medicated feed for not more than the first 3 weeks of life.	
		6. Swine; as an aid in reducing spread of leptospirosis	Sole medication; as chlortetracyline hydrochloride	
(vi) 200 to 400		For ducks; for the control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracyline.	Feed in Type C medicated feed to provide from 8 to 28 mg per pound of body weight per day depending upon age and severity of disease, for not more than 21 d; as the calcium complex of chlortetracyline equivalent to chlortetracyline hydrochloride.	
(vii) 400		1. For turkey poults not over 4 weeks of age; aid in reducing mortality due to paratyphoid caused by *Salmonella typhimurium*.	In low-calcium Type C medicated feed containing 1 pct total calcium with not less than 0.45 pct calcium from calcium sulfate; as chlortetracyline hydrochloride.	
		2. Swine; as an aid in reducing shedding of leptospirae; as an aid in reducing the abortion rate of swine and the mortiality rate of newborn pigs when leptospirosis is present.	To be fed for 14 d as sole medication; as chlortetracyline hydrochloride.	
(viii) 500		For chickens; aid in the reduction of mortality due to *E. coli* infections suspectible to such treatment.	Not to be fed to laying chickens, as chlortetracyline hydrochloride; in Type C medicated feed containing 0.8 pct dietary calcium; not to be fed continuously for more than 5 d; withdraw 24 h prior to slaughter.	

Table 2

Chlortetracycline Milligrams per pound of body weight per day	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
(i) 0.1		For calves up to 250 lb in weight; growth promotion and feed efficiency.	In milk replacers or starter Type C medicated feed.	
(ii) 0.5		1. For beef cattle over 1,500 lb in weight; aid in prevention of anaplasmosis.	Not to be administered within 48 h of slaughter.	
		2. For calves up to 250 lb in weight; aid in the prevention of bacterial diarrhea.	In milk replacers or starter Type C medicated feed.	
(iii) 5.0		For beef cattle; aid in the elimination of the carrier state of anaplasmosis.	Feed for 60 days; for use in the carrier state only; not to be fed within 10 d of slaughter. Labeling shall include a statement that a positive complement-fixation test at conclusion of a 60-d feeding period does not necessarily establish that anaplasmosis carrier state is still active. To positively establish that the carrier state has been eliminated, inject blood from a suspected carrier into a splenectomized (susceptible) calf.	
(iv) 25 to 70		For calves; growth promotion and feed efficiency.		
(v) 70		1. For feedlot cattle; aid in prevention of liver abscesses.		
		2. For beef cattle up to 700 lb in weight; aid in reduction of bacterial diarrhea; aid in preventon of foot rot.		
		3. For growing cattle; growth promotion and feed efficiency.		
(vi) 85		For horses up to 1 year of age; growth promotion and feed efficiency.	Do not slaughter for food purposes	
(vii) 100		For beef cattle over 700 lb in weight; aid in reduction of bacterial diarrhea; aid in prevention of foot rot.		
(viii) 350		1. For beef cattle; aid in preventon of bacterial pneumonia and shippings fever (hemorrhagic septicemia); aid in reduction of losses due to respiratory infection (infectious rhinotracheitis, shipping fever complex).	Not to be administered within 48 h of slaughter.	
		2. For beef cattle up to 700 lb in weight; aid in prevention of anaplasmosis.	do.	
	Sulfamethazine 350	For beef cattle; aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.	Feed fo 28 d; withdraw 7 d prior to slaughter.	
(ix) 500		For beef cattle 700 to 1,000 lb in weight; aid in prevention of anaplasmosis.	Not to be administered within 48 h of slaughter.	
(x) 750		For beef cattle 1,000 to 1,500 lb in weight; aid in prevention of anaplasmosis.	do.	

(4) Chlortetracycline may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium plus ethopabate as in § 558.58.

(iii) Buquinolate as in § 558.105.

(iv) Clopidol as in § 558.175.

(v) Decoquinate as in § 558.195.

(vi) [Reserved]

(vii) Hygromycin B as in § 558.274.

(viii) Robenidine hydrochloride as in § 558.515.

(ix) Roxarsone as in § 558.530.

(x) Zoalene as in § 558.680.

§ 588.145 Chlortetracycline, penicillin procaine, and sulfamethazine.

(a) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) [Reserved]

(3) [Reserved]

(4) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(5) Type C medicated feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as penicillin procaine and 100 grams of sulfamethazine.

(b) *Approvals.* Type A medicated article: 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and pencillin procaine equivalent in activity to 10 grams of penicillin per pound to 000196 and 010042 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) [Reserved]

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.670 of this chapter.

(f) *Conditions of use.* (1) It is administered to swine for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 7 days prior to slaughter.

§ 558.155 Chlortetracycline, penicillin procaine, and sulfathiazole.

(a) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) [Reserved]

(3) [Reserved]

(4) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(b) *Approvals.* (1) Type A medicated articles: 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and penicillin procaine, equivalent to 10 grams of penicillin per pound, to 025001 in § 510.600(c) of this chapter.

(2) Type A medicated articles: 40 grams of chlortetracycline hydrochloride, 8.8 percent (40 grams) sulfathiazole, and penicillin procaine equivalent to 20 grams of penicillin per pound, to 025001 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) [Reserved]

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.690 of this chapter.

(f) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency in animals up to 6 weeks postweaning. For increased rate of weight gain in animals from 6 to 16 weeks postweaning. Maintenance of weight gains in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery).

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture; withdraw 7 days prior to slaughter; as penicillin procaine and chlortetracycline hydrochloride, as follows:

Minimum Amount of Type C Medicated Feed Article Which the Animal Should Consume

Type of feed	Approximate body weight in pounds	Minimum desired daily feed intake in pounds
Prestarter (up to 6 weeks' postweaning)	20	1
Starter (up to 6 weeks' postweaning)	[illegible]	1½
Grower (6 to 16 weeks' postweaning)	[illegible]	2
Finisher (6 to 16 weeks' postweaning)	150	[illegible]

§ 558.175 Clopidol.

(a) [Reserved]

(b) *Approvals.* (1) Type A medicated articles: 25-percent to 025700 in § 510.600(c) of this chapter.

(2) [Reserved]

(3) Type A medicated article combinations of clopidol 25 percent, roxarsone 10 percent, and bacitracin methylene disalicylate, 4, 10, 15, or 25 grams per pound to 025700 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 566.160 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i). *Amount per ton.* Clopidol 113.5 grams (0.0125 percent).

(a) Indications for use. Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(*b*) *Limitations.* Do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation.

(*b*) *Limitations.* Do not feed to chickens over 16 weeks of age withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent) plus bacitacin, 4–25 grams.

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation; increased rate of weight gain..

(*b*) *Limitations.* Do not feed to chickens over 16 weeks of age withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by 046573 in § 510.600(c) of this chapter; or as bacitracin zinc provided by 012769.

(iv) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus bacitracin zinc, 5 to 25 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(*b*) *Limitations.* Feed continuously as sole ration. Bacitracin zinc as provided by 012769 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus bacitracin methylene disalicylate, 4 to 50 grams per ton.

(*a*) *Indications for use.* For increased rate of weight gain; to aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti.*

(*b*) *Limitations.* Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus lincomycin, 2–4 grams.

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* increase in rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* As lincomycin hydrochloride monohydrate; do not feed to chickens over 16 weeks of age.

(2) *Broiler chickens and replacement chickens.* (i) *Amount per ton.* Clopidol, 113.5 or 227 grams (0.0125 or 0.025 percent).

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(*b*) *Limitations.* Feed up to 16 weeks of age if intended for use as caged layers; feed continuously as the sole ration; withdraw 5 days before slaughter if given at the level of 0.025 percent in type C medicated feed or reduce level to 0.0125 percent 5 days before slaughter.

(ii) *Amount per ton.* 113.5 grams (0.0125 percent) clopidol with 200 grams chlortetracycline.

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti,* and infectious synovitis caused by *Mycoplasma synoviae.*

(*b*) *Limitations.* Feed continuously as sole ration from the time chicks are

placed in floor pens, up to 21 days of age.

(3) [Reserved]

(4) *Replacement chickens*—(i) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent).

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus roxarsone 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati; growth promotion and feed efficiency; improving pigmentation.*

(*b*) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(5) *Turkeys*—(i) Amount per ton. Clopidol, 113.5 or 227 grams (0.0125 or 0.025 percent).

(ii) *Indications for use.* Aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi.*

(iii) *Limitations.* For turkeys grown for meat purposes only; to be administered continously in Type C medicated feed at 0.0125 or 0.025 percent clopidol as the sole ration depending upon management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.

§ 558.185 Coumaphos.

(a) [Reserved]

(b) *Approvals.* (1) Type A medicated articles: 1.12, 2.0, 11.2, and 50 percent for use as in paragraph (f) of this section to 000859 in § 510.600(c) of this chapter.

(2) Type A medicated articles: 1.12 and 11.2 percent for use as in paragraph (f)(1)(ii) of this section to 017800.

(c) [Reserved]

(d) *Special considerations.* Warning—Coumaphos is a cholinesterase inhibitor. Do not use this product simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Atropine is antidotal.

(e) *Related tolerances.* See 40 CFR 180.189.

(f) *Conditions of use.* It is used as follows:

(1) *Beef and dairy cattle*—(i) *Amount.* Coumaphos 0.00012 lb. (0.054 gram) per 100 lb. body weight per day.

(a) *Indications for use.* As an aid in the reduction of fecal breeding flies through control of fly larvae.

(b) *Limitations.* Feed for the duration of fly season in a feed containing 0.0033 percent not over 0.0066 percent coumaphos; do not feed to animals less than 3 months old; not for use in pelleted feed.

(ii) *Amount.* Coumaphos, 0.0002 lb. (0.091 gram) per 100 lb. body weight per day.

(a) *Indications for use.* Control of gastrointestinal roundworms (*Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Trichostrongylus spp.*).

(b) *Limitations.* Feed for 6 consecutive days in the normal grain ration to which the animals are accustomed but not in rations containing more than 0.1 percent coumaphos; do not feed to animals less than 3 months old do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks; do not feed in conjunction with oral drenches or with feeds containing phenothiazine. Should conditions warrant, repeat treatment at 30-day intervals.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* Administer continuously for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* Administer before the onset of production; diagnosis by competent personnel is essential; administer continuously for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

§ 558.195 Decoquinate.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated articles: 6 percent to 011801 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) *Related tolerances.* See § 556.170 of this chapter.

(f) *Special considerations.* Bentonite should not be used in decoquinate containing medicated feeds.

(g) *Conditions of use.* (1) It is used as follows:

Table 1

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27.2 (0.003 pct)		Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*	Do not feed to laying chicken	011801
	Bacitracin 10 to 50	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as bacitracin zinc provided by 012769 in sec. 510.600(c) of this chapter.	011801
	Chlortetracycline 200	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria Tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti;* for the treatment of chronic respiratory disease (air-sac infection), prevention of synovitis.	Do not feed to laying chickens; in low calcium Type C medicated feed articles containing 0.8 pct of calcium; not to be fed continuously for more than 8 weeks; as chlortetracycline hydrochloride provided by 010042 in sec. 510.600(c) of this chapter.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* growth promotion and feed efficiency; improving pigmentation.	Do not feed to laying chickens; withdraw 5 d before slaughter, as sole source of organic arsenic.	011801
	Lincomycin 2	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria Tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as lincomycin hydrochloride monohydrate provided by 000009 in sec. 510.600(c) of this chapter.	000009, 011801
	Roxarsone 11 to 45 (0.0012–0.005 pct) plus bacitracin 2 to 50.	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. Mivati, E. maxima,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin zinc provided by 012769 in sec. 510.600(c) of this chapter; as roxarsone provided by 017210.	011801

Table 2

Decoquinate	Combination in grams per ton	Indications for use	Limitations	Sponsor
22.7 mg per 100 lb of body weight per day (0.5 mg per kilogram).		Cattle; as an aid in the prevention of coccidiosis in ruminating calves and cattle caused by *Eimeria bovis* and *E. zurnii.*	Administer as a feed containing 0.0015 to 0.003 pct decoquinate, or 0.05 to 0.5 pct decoquinate. Feed for at least 28 d during periods of coccidiosis or when it is likely to be a hazard. Do not feed to breeding animals or cows producing milk for food. .0015—.003 pct feed should be consumed within 7 d of manufacture, 0.5—.5 pct feed within 2 mo.	011801

§ 558.205 Dichlorvos.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 9.6 percent to 025001 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feed to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Type C medicated feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing dichlorvos or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(e) *Related tolerances.* See § 556.180 of this chapter.

(f) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* Dichlorvos, 348 grams (0.0384 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp. p.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 3 consecutive days.

(2) *Amount per ton.* Dichlorvos, 479 grams (0.0528 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp. p.*), large roundworm (*Ascaris suum*), and the

thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

((ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

(3) *Amounts per ton.* Dichlorvos, 334–500 grams (0.0366–0.0550 percent).

(i) *Indications for use.* An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth-stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp. p.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.

(ii) *Limitations.* For pregnant swine; mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.

§ 558.240 Dimetridazole.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 30 percent to 017210 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.210 of this chapter.

(e) *Conditions of use.* It is used for turkeys as follows:

(1) *Amount per ton.* 136 to 182 grams (0.015 to 0.02 percent).

(i) *Indications of use.* For prevention of blackhead (histomoniasis, infectious enterohepatitis), growth promotion and feed efficiency.

(ii) *Limitations.* Feed continuously; do not feed to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

(2) *Amount per ton.* 544 to 725 grams (0.06 to 0.08 percent).

(i) *Indications for use.* As an aid in the control of blackhead (histomoniasis, infectious enterohepatitis).

(ii) *Limitations.* Feed for not more than 7 days; do not feed to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

§ 558.248 Erythromycin thiocyanate.

(a) *Approvals.* Type A medicated articles: 2.2 percent (10 grams per pound) to 043731 in § 510.600(c) of this chapter for use in swine feed; 11 percent (50 grams per pound) to 043731 for chicken, turkey, and cattle feed.

(b) [Reserved]

(c) *Special considerations.* The levels of antibiotic are expressed in terms of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(d) *Related tolerances.* See § 556.230 of this chapter.

(e) *Conditions of use*—(1) It is used as follows:

Erythromycin thiocyanate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 18.5		Chickens; growth promotion and feed efficiency		
(ii) 9.25 to 18.5		Turkeys; growth promotion and feed efficiency	For turkeys not over 12 weeks of age	
(iii) 9.25 to 64.75		Swine; increase in weight grain, improved feed efficency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).	Starter ration for animals up to 35 lb body weight	043731
(iv) 18.5		Laying chickens; aid in increasing egg production		
(v) 92.5		1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.	
		2. Chickens; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter	
		3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress	
(vi) 185		1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
		2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory dis-	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes.	

(2) It is used for feedlot beef cattle at 37 milligrams per head per day as an aid in stimulating growth and improving feed efficiency.

(3) Erythromycin thiocyanate may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Arsanilic acid as in § 558.62.

(iv) Zoalene as in § 558.680.

§ 558.254 Famphur.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 13.2 and 33.3 percent to 010042 in § 510.600(c) of this chapter.

(c) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Related tolerances.* See 40 CFR 180.233.

(e) *Conditions of use.* It is used for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry diary cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

§ 558.262 Furazolidone.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 10, 50, and 100 grams per pound to 000007 and 011801 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.290 of this chapter.

(e) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 150 grams (0.0165 percent).

(i) *Indications for use.* In sows, for prevention of bacterial scours in baby pigs; growth promotion while on medication.

(ii) *Limitations.* Feed 1 week before farrowing and 2 weeks after farrowing.

(2) *Amount per ton.* 100 to 200 grams (0.011 to 0.022 percent).

(i) *Indications of use.* Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication.

(ii) *Limitations.* Feed 100 grams per ton for 5 weeks; or 150 grams per ton for 3 weeks; or 200 grams per ton for 2 weeks.

(3) *Amount per ton.* 300 grams (0.033 percent).

(i) *Indications for use.* Treatment of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication.

(ii) *Limitations.* Feed 10 to 14 days.

§ 558.266 Griseofulvin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 35 percent (160 grams per pound) to 000085 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used for chinchillas as follows:

(1) *Amount.* 160 milligrams per pound (0.0353 percent).

(2) *Indications for use.* Prevention, treatment, and control of fungal infections caused by *Trichophyton,* and as an aid in the prevention of fur chewing associated with these fungal infections.

(3) *Limitations.* Administer as sole ration.

§ 558.274 Hygromycin B.

(a) *Approvals.* Type A medicated article: 2.4 and 8 grams to 000986 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) [Reserved]

(d) *Related tolerances.* See § 558.330 of this chapter.

(e) *Conditions of use.* It may be used as follows:

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12		Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Withdraw 3 days before slaughter	000986
	Bacitracin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or bacitracin zinc, withdraw 3 days before slaughter.	
	Bacitracin plus penicillin (100 to 200 of combination).	1. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Feed containing not less than 25% of penicillin plus not less than 50% of bacitracin; as penicillin procaine plus bacitracin methylene disalicylate; withdraw 3 days before slaughter.	
		2. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Combination containing not less than 50% nor more than 75% of bacitracin, except that it contains not more than 125 g of penicillin; as penicillin procaine plus bacitracin zinc, withdraw 3 days before slaughter.	
		3. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Combination containing 50% to 75% bacitracin, but not more than 125 g of penicillin, as penicillin procaine, withdraw 3 days before slaughter.	
	Chlortetracycline 100 to [illegible]	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride; withdraw 3 days before slaughter.	
	Penicillin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As penicillin procaine, withdraw 3 days before slaughter	
	Penicillin plus streptomycin (90 to 180 of combination).	do	Feed containing 16.7% of penicillin; as penicillin procaine plus streptomycin sulfate; withdraw 3 days before slaughter.	
	Tylosin 4 to 50	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); growth promotion and feed efficiency.	As tylosin phosphate withdraw 3 days before slaughter	000986
(ii) 12		Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostenum dentatum*) and whipworms (*Trichuris suis*).	Withdraw 15 days before slaughter	000986
	Chlortetracycline 100 to 200.	Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostenum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial swine enteritis.	As chlortetracycline hydrochloride; withdraw 15 days before slaughter	
Tylosin 10 to 100		Swine: Control of infestations of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*); growth promotion and feed efficiency.	As tylosin phosphate; withdraw 15 days prior to slaughter, feed continuously as follows:	000986

Animal wt (lbs.)	Amount of tylosin (g/t)
Up to 40	20 to 100
41 to 100	20 to 40
101 to market wt	10 to 20

(2) Hygromycin B may also be used in combination with:
(i) Amprolium as in § 558.55.
(ii) Zoalene as in § 558.680.

§ 558.295 Iodinated casein.

(a) *Approvals.* See 017762 in § 510.600(c) of this chapter.
(b) *NAS/NRC status.* The use of this drug is NAS/NRC reviewed and found effective. Applications for these uses need not include efficacy data as required by § 514.111 of this chapter but may require bioequivalency or safety data.
(c) *Conditions of use.* (1) *Ducks.*—(i) *Amount per ton.* 100 to 200 grams.
(ii) *Indications for use.* For increased rate of weight gain and improved feathering in growing ducks.
(2) *Dairy cows*—(i) *Amount per pound.* ½ to 1½ grams per 100 lb of body weight.
(ii) *Indications for use.* For increased milk production in dairy cows.
(iii) *Limitations.* This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration must be accompanied with increased feed intake; administration may increase heat sensitivity of the animal.

§ 558.305 Ipronidazole.

(a) [Reserved]
(b) *Approvals.* Type A medicated articles: 12.5 percent to 000004 in § 510.600(c) of this chapter.
(c) [Reserved]
(d) *Related tolerances.* See § 556.340 of this chapter.
(e) [Reserved]
(f) *Conditions of use.* It is used for turkeys as follows:
(1) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent).
(i) *Indication for use.* As an aid in the prevention of blackhead (histomoniasis). For increased rate of weight gain and improved feed efficiency.
(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food.
(2) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent) plus sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).
(i) *Indications for use.* As an aid in the prevention of blackhead (histomoniasis) and coccidiosis caused by all Eimeria species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis;* bacterial infections due to *P. multocida* (fowl cholera).
(ii) *Limitations.* Withdraw 5 days before slaughter. Do not feed to turkeys producing eggs for food.
(3) *Amount per ton.* Ipronidazole, 227 grams (0.025 percent).
(i) *Indications for use.* For the treatment of blackhead (histomoniasis) in turkeys.
(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food. Feed for 7 days at the 0.025 percent level. Follow treatment with the preventive level (0.00625 percent) of ipronidazole.

§ 558.311 Lasalocid sodium.

(a) [Reserved]
(b) *Approvals.* Type A medicated articles: 68 and 90.7 grams per pound of lasalocid sodium activity to 000004 in § 510.600(c) of this chapter.
(c) [Reserved]
(d) *Related tolerance.* See § 556.347 of this chapter.
(e) *Conditions of use.* It is used for broiler or fryer chickens as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 68 (0.0075 pct) to 113 (0.0125 pct).		For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	For broiler or fryer chickens only, feed continuously as the sole ration; withdraw 3 days before slaughter.	000004
(2) 68 (0.00075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* and as an aid in the reduction of lesions due to E. tanella.	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter, roxarsone provided by 017210 and 011801 in sec. 510.600(c) of this chapter.	000004
(3) 68 (0.0075 pct)	Lincomycin 2 (0.00044 pct).	For the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima.* and *E. necatrix;* for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration, withdraw 5 days before slaughter; finished feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	000004
(4) 68 (0.0075 pct)	Bacitracin 10 to 50	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 3 days before slaughter; bacitracin methylene disalicyiate provided by 046573 in § 510.600(c) of this chapter.	000004

§ 558.315 Levamisole hydrochloride (equivalent).

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* Type A medicated articles: 227 grams per pound to No. 043781 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) *Related tolerances.* See § 556.350 of this chapter.

(f) [Reserved]

(g) *Conditions of use.* It is used as follows:

(1) *Cattle*—(i) *Amount per pound.* 0.36–3.6 grams (0.08–0.8 percent).

(ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Hawmonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), and lungsworms (*Dictyocaulus*).

(iii) *Limitations.* Administer mixed thoroughly in one half the usual amount of morning feed; the mixed feed should be consumed within 6 hours; when the mixed feed is consumed resume normal feeding; mixed Type C medicated feed is to be fed at the rate of 0.36 grams of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feed only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine*—(i) *Amount per pound.* 0.36 grams (0.08 percent).

(ii) *Indications for use.* Treatment of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), swine kidney worms (*Stephanurus dentatus*).

(iii) *Limitations.* It is recommended that regular feed be withheld overnight and Type C medicated feed administered the following morning; feed 1 lb. of 0.08 percent Type C medicated feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when mixed feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after Type C medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

§ 558.325 Lincomycin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 4 grams per pound to 000009 in § 510.600(c) of this chapter for use as in paragraphs (f)(1) and (f)(3) of this section; 20 grams per pound to 000009 for use as in paragraph (f) (1), (2), and (3).

(c) [Reserved]

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) [Reserved]

(f) *Conditions of use.* (1) Broilers. It is used as follows:

(i) *Amount per ton.* 2 to 4 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* As lincomycin hydrochloride monohydrate.

(ii) *Amount per ton.* 2 grams.

(*a*) *Indications for use.* For control of necrotic enteritis caused by *Clostridium spp.* or other susceptible organisms.

(*b*) *Limitations.* As lincomycin hydrochloride monohydrate.

(2) *Swine.* It is used as follows:

(i) *Amount per ton.* 40 grams.

(*a*) *Indications for use.* For control of swine dysentery.

(*b*) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not for use in breeding swine; withdraw 6 days before slaughter.

(ii) *Amount per ton.* 100 grams; then 40 grams.

(*a*) *Indications for use.* For treatment and control of swine dysentery.

(*b*) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not for use in breeding swine; withdraw 6 days before slaughter.

(iii) *Amount per ton.* 100 grams.

(*a*) *Indications for use.* For treatment of swine dysentery.

(*b*) *Limitations.* Feed as sole ration for 3 weeks or until signs of disease disappear; not for use in breeding swine; withdraw 6 days before slaughter.

(3) Lincomycin may also be used for broilers in combination with:

(i) Amprolium, ethopabate, and roxarsene as in §§ 558.58 and 558.530.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Clopidol as in § 558.175.

(iv) Buquinolate as in § 558.105.

(v) Decoquinate as in § 558.195.

(vi) Zoalene as in § 558.680.

(vii) Monensin as in § 558.355.

(viii) Robenidine hydrochloride as in § 558.515.

(ix) Roxarsone and monensin sodium as in §§ 558.355 and 558.530.

(x) Lasalocid sodium as in § 558.311.

(xi) Nicarbazin and roxarsone as in § 558.366.

(xii) Nicarbazin as in § 558.366.

§ 558.342 Melengestrol acetate.

(a) *Approvals.* Dry Type A medicated articles: 100 milligrams of melengestrol acetate per pound; liquid Type A medicated articles: 500 milligrams of melengestrol acetate per pound, to 000009 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) [Reserved]

(d) *Related tolerances.* See § 556.380 of this chapter.

(e) *Conditions of use.* It is used for heifers as follows:

(1) *Amount.* 0.25 to 0.50 milligram per head per day.

(2) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(3) *Limitations.* Heifers being fed for slaughter; withdraw 48 hours prior to slaughter.

§ 558.355 Monensin.

(a) *Specifications.* Monensin is present as monensin or the sodium salt. A mininum of 90 percent of monensin activity is derived from monensin A.

(b) *Approvals.* Approvals for Type A medicated articles containing specified levels of monensin activity to firms identified in § 510.600(c) of this chapter for conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 36.3 (for export only), 44, 45, or 60 grams per pound, paragraph (f) (1)(i) and (4) of this section.

(2) To 000986: 110 grams per lb., paragraph (f)(1) (i), (iii), (iv), (v), (ix), and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone; 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 012286; 303.5 grams per ton, as monensin sodium, with .0138 percent roxarsone, paragraph (f)(1)(ii).

(5)–(6) [Reserved]

(7) To 000986: 20, 30, 45, or 60 grams per pound, as monensin sodium, paragraph (f)(3).

(c) [Reserved]

(d) *Special considerations.* (1) Type C medicated chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2) Type C medicated cattle feeds containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.

(3)–(4) [Reserved]

(5) Liquid Type C medicated feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(e) *Related tolerances.* See § 556.420 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 72 hours before slaughter; as monensin or monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone, 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as bacitracin methylene disalicylate provided by 046573 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as bacitracin zinc provided by 012769 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as bacitracin zinc provided by 012769 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 gram. See § 558.95(e)(1)(vi).

(vii) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See § 558.95(e)(1)(vii).

(viii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli.*

(*b*) *Limitations.* Withdraw 72 hours before slaughter; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.

(ix) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; to be fed as a sole ration, withdraw 72 hours before slaughter; as monensin sodium.

(x) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

(*a*) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by 017210 in § 510.600(c) of this chapter; as monensin sodium provided by 000986; as lincomycin provided by 000009; as a combination provided by 000009.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(*a*) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by 017210 in § 510.600(c) of this chapter; as monensin sodium provided by 000986; as lincomycin provided by No. 000009; as a combination provided by 000009.

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 25 grams, and roxarsone, 11.3 to 22.7 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati;* for increased rate of weight gain and for improved feed efficiency.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by 000986 in § 510.600 of this chapter; as bacitracin methylene disalicylate provided by 046573; as roxarsone provided by 011801.

(2) [Reserved]

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–30 grams.

(a) Indications for use. Improved feed efficiency.

(b) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously at a rate of 50 to 360 milligrams of monensin per head per day; as monensin sodium. Type C medicated feeds may be manufactured from monensin liquid Type B or Type C medicated feeds which contain a minimum of 20 percent molasses in combination with any of the following feed ingredients or their equivalents: condensed fermentation solubles, whey, ammonium, polyphosphate, sodium hydroxide. phosphoric acid, fat, sulfuric acid, attapulgite clay, water, urea, vitamins, and/or minerals; a pH of 4.3 to 6; agitate until homogenous prior to use; mix thoroughly with grain and/or roughage prior to feeding. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(ii) *Amount per ton.* Monensin, 10 to 30 grams, plus tylosin, 10 grams.

(a) Indications for use. Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Sphaerophorus necrophorus* and *Corynebacterium pyogenes.*

(b) Limitations. Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 100 to 360 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to formulations containing monensin (ingestion of monesin by horses has been fatal).

(iii) *Amount per ton.* Monensin, 25 to 400 grams.

(a) Indications for use. Increased rate of weight gain.

(b) Limitations. Feed to pasture cattle (slaughter, stocker, and feeder) weighing more than 400 pounds. Feed at the rate of not less than 50 nor more than 200 milligrams per head per day in a minimum of 1 pound of feed, as monensin sodium. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal).

(4) *Replacement chickens intended for use as cage layers*—(i) *Amount per ton.* Monensin, 90 to 110 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as monensin sodium; do not feed to chickens over 16 weeks of age.

§ 558.365 Nequinate.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles; 4 percent nequinate to 017800 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.440 of this chapter.

(e) *Special considerations.* Do not use in Type B or Type C medicated feed containing bentonite.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinate, 18.16 grams.

(a) Indications for use. An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) Limitations. Feed continuously as the sole ration.

(ii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) Indications for use. An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; for improving pigmentation.

(b) Limitations. Feed continuously as sole ration throughout the starting period; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus oxytetracycline, 200 grams.

(a) Indications for use. For control of complicated chronic respiratory disease (air-sac infection), infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).

(b) Limitations. As monoalkyl (C_8-C_{18}) trimethylammonium oxytetracycline as provided by No. 000069 in § 510.600(c) of this chapter.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

§ 558.336 Nicarbazin.

(a) *Approvals.* Type A medicated article: 25 percent nicarbazin to 000006 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) [Reserved]

(e) *Conditions of use.* It is used for chickens as follows:

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
113.5 (0.0125 pct)[1] ..	.....	Chickens; aid in preventing outbreaks of cecal (*Eimena tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis[1].	Feed continously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do no use in flusing mashes; do not feed to laying hens; withdraw 4 days before slaughter.	000006
	Lincomycin 2 (0.00044 pct).	Broiler chickens; aid in preventing outbreaks of cecal (*Eimena tenella*) and intestinal (*E. acervulina, E. maxima E. necatrix* and *E. brunetti*) coccidiosis; for increased rate of weight gain.	.....do.....	000006
113.5 (0.0125 pct).....	Roxarsone 22.7 (0.0025)	.....do.....	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; as sole source of organic arsenic; do not use a treatment for coccidiosis; do not use in flushing mashes; do not feet to laying hens; withdraw 5 days before slaughter.	000006
	Roxarsone 22.7 (0.0025) plus linocomycin 2 (0.0004).	.....do.....	.....do.....	000006

[1] These claims are NAS/NRC reviewed and are found effective. Applications for these uses need not include the effectiveness data specfied by § 514.111 of this chapter

§ 558.367 Niclosamide.

(a) *Approvals.* Type A medicated articles: 66 percent to No. 000859 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Conditions of use.* It is used for laboratory mice as follows:

(1) *Amount per ton.* 6.6 pounds (0.033 percent).

(2) *Indications for use.* Control of the mouse tapeworm *Hymenolepis nana.*

(3) *Limitations.* Feed daily for 7 consecutive days. Do not administer other drugs during treatment. If reinfection occurs, treatment may be repeated after 30 days. Do not feed to sick or debilitated animals or animals under severe stress. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. When mixed according to directions and fed free choice, the Type C medicated feed will provide a daily dose of 500 milligrams per kilogram of body weight.

§ 558.370 Nitrofurazone.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals:* Type A medicated articles: 50 grams per pound to 000007 and 011801 in § 510.600(c) of this chapter.

(d) *Conditions of use.* It is used for mink as follows:

(1) *Amount per ton.* 100 to 200 grams (0.011 to 0.022 percent).

(i) *Indications for use.* Treatment of gray diarrhea.

(ii) *Limitations.* Feed 100 grams per ton for 3 days, then 200 grams per ton for 21 days (amount of active ingredient calculated on Type C medicated feed before water added); do not repeat treatment. Discard unused Type C medicated feed every 24 hours.

(2) *Amount per ton.* 100 grams (0.011 percent).

(i) *Indications for use.* Control of gray diarrhea.

(ii) *Limitations.* Feed continously during susceptible period, not to exceed 90 days (amount of active ingredient calculated on Type C medicated feed before water added). Discard unused mixed Type C medicated feed every 24 hours.

§ 558.376 Nitromide and sulfanitran.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 25 percent nitromide, 30 percent sulfanitran, with or without 5 percent roxarsone to 017210 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See §§ 556.220 and 556.680 of this chapter.

(e) *Condtions of use.* It is used for chickens as follows:

(1) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (0.03 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A medicated articles containing not more than 25 percent nitromide and 30 percent sulfanitran.

(2) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (0.03 percent), plus 45.4 grams per ton roxasone (0.005 percent).

(i) *Indications for use.* Prevention of coccidiosis caused by *Eimeria tenella, E. necatrix,* and *E. acervulina; growth promotion and feed efficiency; improving pigmentation.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A medicated articles containing not more than 25 percent nitromide, 30 percent sulfanitran, and 5 percent roxarsone; as sole source of organic arsenic.

§ 558.415 Novobiocin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 25 grams of novobiocin activity per pound to 000009 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) [Reserved]

(e) *Related tolerances.* See § 556.460 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 200 grams of novobiocin activity per ton; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(*b1*) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 350 grams of novobiocin activity per ton; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount. Novobiocin, 4–5 mgs. per lb. body weight per day.*

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptable to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 200 grams of novobiocin activity per ton; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin. 5–8 mgs. per pound of body weight per day.

(*a*) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound of body weight per day.

(*b*) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 200 grams of novobiocin activity per ton; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per pound of body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 350 grams of novobiocin activity per ton; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations.* Administer, as sole ration, Type C medicated feed which contains not less than 200 grams of novobiocin activity per ton; feed for 7 days.

(4) *Ducks*—(i) *Amount.* Novobiocin, 350 grams per ton.

(ii) *Indications for use.* Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida,* susceptible to novobiocin.

(iii) *Limitations.* Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary,

repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

§ 558.430 Nystatin.

(a) [Reserved].

(b) *Approvals.* Type A medicated articles: 20 grams of nystatin activity per pound to 000003 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.470 of this chapter.

(e) *Conditions of use.* It is used for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

§ 558.435 Oleandomycin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 5 grams of oleandomycin activity per pound to 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 558.480 of this chapter.

(e) *Special considerations.* Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin.

(f) *Conditions of use.* It is used as follows:

(1) *Chickens and turkeys*— (i) *Amount per ton.* Oleandomycin, 1–2 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton.* Oleandomycin, 5–11.25 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

§ 558.450 Oxytetracycline.

(a) *Approvals.* Type A medicated articles equivalent of 10 and 50 grams per pound of oxytetracycline hydrochloride to 000069 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Special considerations.* The amount of oxytetracycline is expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(d) *Related tolerances.* See § 556.500 of this chapter.

(e) *Conditions of use.* (1) It is used as follows:

Table 1.—*For Chickens and Turkeys*

Oxytetracycline in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50		Chickens and turkeys; during times of stress, for prevention of diseases named in this section caused by organisms susceptible to the named levels of the oxytetracycline salt.	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline	
(ii) 50 to 100		1. Chickens; prevention of blue comb (nonspecific infectious enteritis).	do	
		2. Chickens and turkeys; prevention of early mortality of chicks and poults due to organisms susceptible to the oxytetracycline salt.	For chicks (1st 2 weeks of life); for poults (1st 4 weeks of life), as mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline.	
		3. Turkeys; prevention of hexamitiasis	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline	
(iii) 100 to 200		1. Chickens; prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory mortality and severity during outbreaks; prevention of fowl cholera.	do	
		2. Chickens; treatment of blue comb (nonspecific infectious enteritis); prevention of infectious synovitis; control of complicated chronic respiratory disease (air-sac infection) by lowering mortality and severity of disease during outbreaks; reduction of lesion and mortality due to organisms susceptible to oxytetracycline in the presence of complicated chronic respiratory disease (air-sac infection).	As mono-alkyl (C_8-C_{14}) trimethly ammonium oxytetracycline in low-calcium Type C medicated feed containing 0.18 pct to 0.55 pct dietary calcium; not to be fed continuously for more than 5 d; low calcium Type C medicated feed may be fed for a total of 3 to 5 d periods through the 1st 10 weeks of life with an interim period of 5 d between each low-calcium feeding. Not to be fed to laying chickens.	
		3. Turkeys; control of infectious sinusitis; prevention of infectious synovitis.	As mono-alkyl (C_8-C_{16}) trimethyl ammonium oxytetracycline	
		4. Turkeys; control blue comb (nonspecifc infectious enteritis, mud fever); treatment of hexamitiasis.	do	
(iv) 200		1. Turkeys; control of infectious synovitis	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline	
		2. Chickens; prevention of avian infectious hepatitis; prevention and control of *E. tenella*, cause of cecal coccidiosis, caused by *E. tenella*.	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline in low-calcium Type C medicated feed containing 0.18 pct to 0.55 pct dietary calcium; not to be fed continuously for more than 5 d; low-calcium Type C medicated feed may be fed for a total of 35-d periods through the 1st 10 weeks of life with an interim period of 5 d between each low-calcium feeding. Not to be fed to laying chickens.	
		3. Chickens; control of infectious synovitis	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline	
		4. Chickens; control of fowl cholera during periods of outbreaks.	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline; in low-calcium Type C medicated feed containing 0.18 pct to 0.55 pct dietary calcium; for 2 weeks from outbreak of disease, 5 d of low calcium and the remaining period on normal calcium; not to be fed to laying chickens.	
	Monensin 90 to 110	Broiler chickens; for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati*, and *E. maxima*.	Withdraw 72 h before slaughter; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.	000069
	Nequinate 18.16 (0.002 pct).	Broiler or fryer chickens; as an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati*. For control of complicated chronic respiratory disease (air-sac infections) infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).	As mono-alkyl (C_8-C_{14}) trimethyl ammonium oxytetracycline	
(v) 500		Broiler chickens; as an aid in the reduction of mortality due to air-sacculitis (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.	Feed for 5 d as sole ration; treat at first clinical signs of disease; do not feed to laying hens; withdraw 24 hr prior to slaughter.	000069

Table 2.—*For Cattle*

Oxytetracycline in milligrams per head per day	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
75 to 80		Beef cattle; reduction of the incidence and severity of liver abscesses.	For beef cattle weighing over 400 lb; as mono-alkyl (C_8-C_{18}) trimethyl-ammonium oxytetracycline.	

Table 3.—*For Fish*

Oxytetracycline	[redacted]	Indications for use	Limitations	Sponsor
(i) 250 mg per kilogram of fish per day (11.35 g per 100 lb of fish per day).		Pacific salmon; for marking of skeletal tissue	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in Type C medicated feed containing oxytetracycline hydrochloride or mono-alkyl (C_8-C_{18}) trimethyl-ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of type D article.	
(ii) 2.5 to 3.75 g per 100 lb of fish per day.		1. Salmonids; control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens*, and pseudomonas disease.	Administer as mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline in Type C medicated feed for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of type C medicated feed; do not administer when water temperature is below 9° C (48.2° F).	
		2. Catfish; control of bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens* and pseudomonas disease.	Administer as mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline in Type C medicated feed for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of Type C medicated feed; do not administer when water temperature is below 16.7° C (62° F).	

(2) Oxytetracycline may also be used in combination with:
(i) Robenidine hydrochloride as in § 558.515.
(ii) [Reserved]

§ 558.460 Penicillin.

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.
(b) [Reserved]
(c) [Reserved]
(d) [Reserved]
(e) *Related tolerances.* See § 556.510 of this chapter.
(f) *Conditions of use.* (1) It is used as follows:

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 1.5 to 42.5	Streptomycin 7.5 to 48.5.	Swine; growth promotion and feed efficiency	Feed not more than 50 g of Type C medicated feed containing at least 1.5 g of penicillin and at least 7.5 g of streptomycin; as streptomycin sulfate.	
(ii) 2.4 to 38.0	Streptomycin 12.0 to 47.6.	Chickens and turkeys; growth promotion and feed efficiency.	Feed not more than 50 g of Type C medicated feed containing at least 2.4 g of penicillin and at least 12 g of streptomycin; as streptomycin sulfate.	
(iii) 2.4 to 50		Chickens, turkeys, and pheasants; growth promotion and feed efficiency.		
(iv) 5 to 20		Quail; growth promotion and feed efficiency	Quail, not over 5 weeks of age	
(v) 10 to 50		Swine; growth promotion and feed efficiency		
(vi) 22.5 to 50 (of combination).	Streptomycin	Chickens; maintaining or increasing egg production	Type C medicated feed contains 16.7 pct of penicillin; as penicillin procaine, as streptomycin sulfate.	
(vii) 45 to 90 (of combination).	do	Swine; aid in the prevention of bacterial swine enteritis	do	
(viii) 50 to 100		1. Chickens; prevention of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).		
		2. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		
(ix) 90 (of combination)	Streptomycin	1. Chickens; prevention of early mortality caused by organisms susceptible to penicillin and streptomycin.	For chicks; in starter ration containing 16.7 pct of penicillin; as penicillin procaine, as streptomycin sulfate.	
		2. Swine; treatment of bacterial swine enteritis	Type C medicated feed contains 16.7 pct of penicillin; as penicillin procaine; as streptomycin sulfate.	
(x) 90 to 180 (of combination)	do	1. Chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis)	do	
		2. Turkeys; treatment of infectious sinusitis; blue comb (mud fever), hexamitiasis.	do	
(xi) 90 to 270 (of combination).	do	Swine; treatment of bacterial swine enteritis	Type C medicated feed contains 16.7 pct of penicillin; feed not more than 14 d; as penicillin procaine; as streptomycin sulfate	
(xii) 100		1. Chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis).		
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		

(2) Penicillin may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium plus ethopabate as in § 558.58.

(iii) Bacitracin methylene disalicylate as in § 558.76.

(iv) Bacitracin zinc as in § 558.78.

(v) Buquinolate as in § 558.105.

(vi) Hygromycin B as in § 558.274.

(vii) [Reserved]

(viii) Reserpine as in § 558.505.

(ix) Roxarsone and zoalene as in § 558.680.

(x) Zoalene as in § 558.680.

§ 558.464 Poloxalene.

(a) [Reserved]

(b) *Approvals.* Dry Type A medicated article of 53 percent and liquid Type A medicated article of 99.5 percent to 000007 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A medicated article and liquid Type A medicated article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by preparing a Type B medicated feed prior to preparing the Type C medicated feed. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

§ 558.465 Poloxalene liquid Type C medicated feed article.

(a) [Reserved]

(b) *Approvals.* Type A medicated feed articles: 99.5 percent to No. 000007 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid. Type C medicated feed (1.65-percent weight/weight). Each animal must consume 0.2 pound of Type C medicated feed per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene per pound of liquid Type C medicated feed (2.2 percent weight/weight). Each animal must consume 0.15 pound of Type C medicated feed per 100 pounds of body weight daily for adequate protection. If consumption exceeds 0.2 pound of Type C medicated feed per 100 pounds of body weight daily, cattle should be changed to a Type C medicated feed containing 7.5 grams of poloxalene per pound.

(3) Poloxalene liquid Type A medicated feed must be thoroughly blended and evenly distributed into a liquid Type C medicated feed and offered to cattle in a covered liquid Type C medicated feed feeder with lick wheels. The formula for the liquid Type C medicated feed, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.66 percent, phosphoric acid (75 percent) 3.37 percent, sulfuric acid 1.00 percent, water 10.00 percent, and molasses sufficient to make 100.00 percent, vitamins A and D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C medicated feed must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C medicated feed and to lick wheel feedings. If the medicated feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

§ 558.485 Pyrantel tartrate.

(a) *Approvals.* Type A medicated articles containing pyrantel tartrate to firms identified by drug labeler codes in § 510.600(c) of this chapter for the specific usage indicated in paragraph (e) of this section:

(1) To 000069: 9.6, 19.2, and 80 grams per pound, paragraph (e)(1) through (3); 48 grams per pound, paragraph (e)(1) through (4).

(2) To 017800: 48 grams per pound, paragraph (e)(1) through (3).

(3) To 016968: 9.6 and 19.2 grams per pound, paragraph (e)(1) through (3).

(4) To 026186: 9.6 and 19.2 grams per pound, paragraph (e)(1) through (3).

(5) To 017790: 9.6 and 19.2 grams per pound, paragraph (e)(1) through (3).

(6) To 01803: 9.6 and 19.2 grams per pound, paragraph (e)(1) through (3).

(7) To 017255: 9.6 and 19.2 grams per pound, paragraph (c)(1) through (3).

(b) *[Reserved]*

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations.* (1) Consult veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or C medicated feeds containing bentonite.

(e) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*esophagostomum*) infections.

(ii) *Limitations.* Feed continuously as sole ration; withdraw 24 hours prior to slaughter.

(2) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(ii) *Limitations.* Feed for 3 days as sole ration; withdraw 24 hours prior to slaughter.

(3) *Amount per ton.* 800 grams (0.0881 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* As a single therapeutic treatment; feed at the rate of 1 lb. of Type C. medicated feed per 40 lb. of body weight for animals up to 200 lb. and 5 lb. of Type C medicated feed per head for animals 200 lb. or over; withdraw 24 hours prior to slaughter.

(4) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours or hemorrhage dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large

roundworm (*Ascaris suum*) infections, aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine weighing over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in Type C medicated feed containing less than 15 percent crude protein.

§ 558.515 Robenidine hydrochloride.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 30 grams per pound to 010042 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Special considerations.* Type D medicated feed articles containing robenidine hydrochloride must be fed within 50 days days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

(e) *Related tolerances.* See § 556.580 of this chapter.

(f) *Conditions of use.* It is used for chickens as follows:

(1) *For broiler and fryer chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix.*

(*b*) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter.

(ii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus roxarsone, 22.7–45.4 grams (.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix* and increased rate of weight gain.

(*b*) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter; as sole source of organic arsenic. Roxarsone provided by 017210 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 100 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CFD) caused by *M. gallisepticum* susceptible to chlortetracycline; as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(*b*) *Limitations.* For broiler or fryer chickens only; withdraw 5 days prior to slaughter; do not feed to layers, feed continuously as sole ration; as chlortetracycline hydrochloride provided by 010042 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the treatment of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline; as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline.

(*b*) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; feed continuously as sole ration; as chlortetracycline hydrochloride provided by 010042 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 500 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.

(*b*) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; not to be fed continuously for more than 5 days; as chlortetracycline hydrochloride provided by 010042 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as bacitracin zinc).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix* and, in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as bacitracin zinc provided by 012769 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as bacitracin methylene disalicylate).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix,* and if in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain or if in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as bacitracin methylene disalicylate provided by 046573 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency and as an aid in prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*

(*b*) *Limitations.* Do not feed to laying hens; feed continuously as the sole ration; withdraw 5 days before slaughter; lincomycin as provided by 000009 in § 510.600(c) of this chapter; approval for this combination granted to 000009, § 510.600(c) of this chapter.

(2) *For broiler chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033) percent) plus oxytetracycline, 200 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli.*

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; oxytetracycline as provided by 000069 in § 510.600(e) of this chapter.

§ 558.525 Ronnel.

(a) [Reserved]

(b) *Approvals.* (1) Type A medicated feeds: 18 and 40 percent to 025700 in § 510.600(c) of this chapter.

(2) Type C medicated feed: 5.5 percent in mineral mix to 021930 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Special considerations.* (1) Maximum level permitted in a Type C medicated feed is 6 percent.

(2) Type C medicated feed containing ronnel shall be thoroughly mixed with ground grain for top dressing or with complete ration.

(3) A statement that ronnel-Type C medicated feed is to be used as sole source of ronnel.

(4) "Warning-Ronnel is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after

exposure to cholinesterase inhibiting drugs, pesticides, or chemicals."

(e) *Related tolerances.* See 40 CFR 180.177.

(f) *Conditions of use.* It is used for beef cattle and nonlactating dairy animals as follows:

(1) *Amount.* 0.00078 lb. (0.35 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed for 14 days in Type C medicated feed containing not over 0.26 percent ronnel; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of Type C medicated feed, or if Type C medicated feed has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(2) *Amount.* 0.0018 lb. (0.82 gram) per 100 lb. body weight per day for 7 days.

(i) *Indications for use.* Control of grubs; aid in the reduction of cattle lice, when the drug is used for cattle grub control.

(ii) *Limitations.* Feed for 7 days in Type C medicated feed containing not over 6 percent ronnel; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C medicated feed, or if Type C medicated feed has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(3) *Amount.* 0.01375 lb. (6.24 gram) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii) *Limitations.* Feed 0.25 lb. of a mineral Type C medicated feed in granular form containing 5.5 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C medicated feed, or if Type C medicated feed has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(4) *Amount.* 0.0009 lb. (0.41 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed for 14 days in Type C medicated feed containing 0.3 percent ronnel; withdraw from daily animals 10 days before calving, if dairy cows or heifers freshen during feeding of Type C medicated feed or if Type C mediated feed has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(5) *Amount.* 0.012 lb. (5.5 grams) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii) *Limitations.* Feed 0.2 lb. of mineral Type C medicated feed containing 6 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of Type C medicated feed, or if Type C medicated feed has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment.

§ 558.526 Ronnel liquid Type C medicated feed.

(a) *Approvals.* To 025700 in § 510.600(c) of this chapter, use of 20 percent liquid Type A medicated articles for the manufacture of 0.72 percent liquid Type C medicated feed.

(b) [Reserved]

(c) *Related tolerances.* See 40 CFR 180.177.

(d) *Conditions of use.* (1) It is used as 0.72 percent liquid Type C medicated feed for beef cattle and nonlactating dairy animals for control of grubs.

(2) Both the 7 and 14-day feeding programs require 1.75 pounds of 0.72 percent liquid Type C medicated feed for each 100 pounds of body weight.

(i) Feed for 7 days, 0.25 pound of 0.72 percent liquid Type C medicated feed per 100 pounds of body weight per day.

(ii) Feed for 14 days, 0.25 pound of 0.72 percent liquid Type C medicated feed per 200 pounds of body weight per day.

(3) Must be evenly top-dressed over the grain portion of the ration or over the mixed total ration.

(4) Treat cattle as soon as possible after heel fly activity ceases, and before grubs reach the backs of the animals. Ronnel is not fully effective during the latter stages of grub development, when grubs have reached the backs of animals.

(5) Treat southern area cattle July through September (7 or 14-day treatment). Treat northern area cattle August through October (7-day treatment) or August through December (14-day treatment).

(6) Dairy animals should be treated early in their dry period but only if the dry period occurs between the end of the adult heel fly season and before grubs reach the back of the animal.

(7) Withdraw from dairy animals 10 days before calving. If animals freshen during feeding of a Type C medicated feed, or if Type C medicated feed has not been withdrawn 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment.

(8) Withdraw 10 days prior to slaughter.

(9) Warning—Ronnel is a cholinesterase inhibitor. Do not use simultaneously or within a few days before or after treatment with or exposure to any cholinesterase inhibiting drugs, pesticides, or chemicals.

(10) Use as sole source of ronnel.

(11) Do not feed to animals that are sick, under stress (shipping, dehorning, castration), or that have been weaned within the preceding 3 weeks.

(12) [Reserved]

(13) This drug is toxic to fish. Keep out of lakes, streams, and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not reuse empty container; destroy it by burning or burying in noncroplands away from water supplies.

§ 558.530 Roxarsone.

(a) *Approvals.* Type A medicated articles: 10.20, and 50 percent to 011801 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) [Reserved]

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed articles for chickens and turkeys as follows:

(1) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent).

(2) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) *Limitations.* Withdraw 5 days before slaughter, as sole source of organic arsenic.

(4) *Permitted combinations.* It may also be used in combination with:

(i) Aklomide as in § 558.35.

(ii) Amprolium as in § 558.55.

(iii) Amprolium and ethopabate as in § 558.58.

(iv) Bacitracin methylene desalicylate as in § 558.76.

(v) Bacitracin zinc as in § 558.78.

(vi) Buquinolate as in § 558.105.

(vii) Chlortetracycline as in § 558.128.

(viii) Clopidol as in § 558.175.

(ix) Decoquinate as in § 558.195.

(x) Monensin as in § 558.355.

(xi) Nequinate as in § 558.365.

(xii) Nitromide and sulfanitran as in § 558.376.

(xiii) Robenidine hydrochloride as in § 558.515.

(xiv) Sulfadimethoxine, ormetoprim as in § 558.575.

(xv) Zoalene as in § 558.680.

(xvi) Penicillin and zoalene as in § 558.680.

(xvii) Bambermycins alone and in combination as in § 558.95.

(xviii) Nicarbazin as in § 558.366.

§ 588.565 Styrylpryidinium chloride, diethylcarbamazine (as base).

(a) [Reserved]

(b) *Approvals.* Type C medicated feed: 0.035 percent styrylpyridinium chloride, and 0.021 percent diethylcarbamazine (as base) to 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used for the control of hookworms *(Ancylostoma caninum)* and roundworms *(toxocara canis)* and for the prevention of heartworm disease *(Dirofilaria immitis)* in dogs.

(2) Type C medicated feeds administered to dogs as follows: Maximum stressed dogs are fed an amount of the Type C medicated feed in ounces equal to the dogs body weight in pounds divided by 4. Medium stressed dogs are fed an amount of the Type C medicated feed in ounces equal to the dogs body weight in pounds divided by 4.5. Low stressed dogs are fed an amount of the Type C medicated feed in ounces equal to the dogs body weight in pounds divided by 5. Underweight dogs are fed 10 percent more than the amounts specified in this paragraph. Overweight dogs are fed 10 percent less than the amounts specified in this paragraph, with adjustments made every 7 days until the desired body weight is obtained.

(3) Dogs with established heartworm infections should not be treated with the drug until they have been converted to a negative status. For the prevention of heartworm infestation, the drug should be administered before the mosquito season and as soon as young puppies are born. The drug should be administered continuously during periods of exposure to hookworm, roundworm, and heartworm infestations to control recurring burdens of hookworms and roundworms and prevent the maturation of immature heartworms (third stage infective larvae) into adults.

(4) Federal law restricts this drug to use by or on the order of a licenses veterinarian.

§ 558.575 Sulfadimethoxine, ormetoprim.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 25 percent of sulfadimethoxine and 15 percent of ormetoprim to 000004 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See §§ 556.490 and 556.640 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(*b*) *Limitations.* Feed as sole ration; withdraw 5 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed as sole ration: withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) *Replacement chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.

(3) *Turkeys.*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 56.5 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent) plus ipronidazole, 56.75 grams (0.00625 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E, meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera); and blackhead (histomoniasis).

(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

§ 558.579 Sulfaethoxypyridazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 5.5 percent for swine, 5.5 and 11 percent for cattle, to 010042 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.650 of this chapter.

(e) *Conditions of use.* It is used as follows:

(1) *Swine.*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of bacterial scours, pneumonia, enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.

(iii) *Limitations.* Administer 1,000 grams per ton (0.11 percent) in Type C medicated feed for not less than 4 days nor more than 10 days; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.

(2) *Cattle.*—(i) *Amount.* 25 milligrams per pound body weight per day.

(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastits and metcemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer as top dressing or in mixed feed for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food; for use by or on the order of a licensed veterinarian.

§ 558.582 Sulfamerazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles. 99 percent to 010042 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.660 of this chapter.

(e) *Conditions of use.* It is used for rainbow trout, brook trout, and brown trout as follows:

(1) *Amount.* 10 grams of sulfamerazine per 100 pounds of fish per day.

(2) *Indications for use.* Control of furunculosis.

(3) *Limitations.* Treat for not more than 14 days; do not treat within 3 weeks of marketing or stocking in stream open to fishing.

§ 558.615 Thiabendazole.

(a) [Reserved]

(b) [Reserved]

(c) *Approvals.* In dry Type A medicated articles: 22, 44.1, 66.1 percent. The 66.1 percent level is solely for the manufacture of cane molasses liquid Type C medicated feed article which is mixed in dry feeds. See 000006 in § 510.600(c) of this chapter.

(d) [Reserved]

(e) *Special considerations. Not to be used in Type B or Type C medicated feeds containing bentonite.*

(f) *Related tolerances.* See § 556.730 of this chapter.

(g) *Conditions of use.* It is used as follows:

(1) *Cattle.*—(i) *Amount.* 3 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Namatodirus spp., Oesophagostomum radiatum*).

(*b*) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight as a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats.*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.*, and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats.*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.*, and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after Type C medicated feed in consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.*; less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine.*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (*Ascaris spp.*).

(iii) *Limitations.* Administer continuously Type C medicated feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by Type C medicated feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

§ 558.625 Tylosin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles containing drug substance with diluent or Type B medicated feed containing drug substance with diluent plus vitamins, minerals, and/or other nutrient ingredients to sponsor(s) identified in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section:

(1) To 000986: 40 and 100 grams per pound, paragraphs (f)(1)(ii) through (f)(1)(vi) of this section; 40 grams per pound, paragraph (f)(1)(i) of this section.

(2)–(4) [Reserved]

(5) To 017800: 40 grams per pound, paragraph (f)(1)(i) and (vi) *(a), (b), (c),* and *(d)* of this section.

(6)–(14) [Reserved]

(15) To 026186: 20 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(16)–(26) [Reserved]

(27) To 020275: 40 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(28)–(72) [Reserved]

(c) [Reserved]

(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* It is used as follows:

(i) *For beef cattle—(a) Amount per ton.* 8–10 grams.

(b) Indications for use. For reduction of incidence of liver abscesses caused by *Sphaerophorus necrophorus* and *Corynebacterium pyogenes.*

(c) Limitations. As tylosin phosphate; each animal must receive not more the 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens.*—(*a*) *Amounts per ton.* Tylosin, 800–1000 grams.

(b) Indications for use. To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(c) Limitations. As tylosin phosphate; withdraw 5 days before slaughter; administer in Type C medicated feed to chickens 0 to 5 days of age, follow with second administration in Type C medicated feed for 24 to 48 hours at 3 to 5 weeks of age.

(iii) *Chickens—(a) Amounts per ton.* Tylosin, 4–50 grams.

(1) Indications for use. For increased rate of weight gain and improved feed efficiency.

(2) Limitations. As tylosin phosphate.

(b) [Reserved]

(iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20–50 grams.

(b) Indications for use. For improved feed efficiency.

(c) Limitations. As tylosin phosphate.

(v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.

(b) Indications for use. To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(c) Limitations As tylosin phosphate; withdraw 5 days before slaughter; administer in Type C medicated feed to chickens 0 to 5 days of age, follow with second administration in Type C medicated feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine—(a)—Amount per ton.* Tylosin, 10–100 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(b) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Prevention of swine dysentery (vibrionic).

(2) *Limitations. Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.*

(c) *Amount per ton.* Tylosin, 40–100 grams.

(1) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(2) *Limitations.* Administer in Type C medicated feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3–10 days, 40–100 grams per ton in Type C medicated feed for 2–6 weeks.

(d) *Amount per ton.* Tylosin, 100 grams.

(1) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinits.

(2) *Limitations.* As tylosin phosphate.

(2) [Reserved]

(2) Tylosin may also be used in combination with:

(i) Hygromycin B as in § 558.274.

(ii)–(iii) [Reserved]

(iv) Monesin as in § 558.355.

§ 558.630 Tylosin and sulfamethazine.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles containing drug substances with diluent, or Type B medicated feed containing drug substances with diluent plus vitamins, minerals, and/or other nutrient substances, the drug substances being a combination of equal amounts of tylosin and sulfamethazine, to sponsor(s) identified in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section:

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i) of this section.

(2)–(4) [Reserved]

(5) To 017800: 40 grams per pound each, paragraph (f)(2)(ii) of this section.

(6) To 017139: 20 grams per pound each, paragraph (f)(2)(ii) of this seciton.

(c)–(d) [Reserved]

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(f) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinits; lowering the incidence and severity of *Bordetella bronchiseptica* rhinits; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*P. multocida* and/or *C. pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinits; lowering the incidence and severity of *Bordetella bronchiseptica* rhinits; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(3) *Limitations.* As tylosin phosphate; withdraw 15 days before slaughter.

§ 558.635 Virginiamycin.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 2.2 percent virginiamycin activity (10 grams per pound), 11 percent virginiamycin activity (50 grams per pound), and 50 percent virginiamycin activity (227 grams per pound) to 000007 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.750 of this chapter.

(e) *Special considerations.* (1) Not for use in breeding swine over 120 pounds.

(2) Dilute Type A medicated article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of feed.

(3)–(4) [Reserved]

(f) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 100 grams for 2 weeks.

(i) *Indications for use.* Treatment of swine dysentery in nonbreeding swine.

(ii) *Animal weight.* Over 120 pounds.

(2) *Amount per ton.* 100 grams for 2 weeks, 50 grams thereafter.

(i) *Indications for use.* Treatment and control of swine dysentery.

(ii) *Animal weight.* Up to 120 pounds.

(3) *Amount per ton.* 25 grams.

(i) *Indications for use.* Aid in control of swine dysentery. For use in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.

(ii) *Animal weight.* Up to 120 pounds.

(4) *Amount per ton.* Administer 10 grams per ton from weaning to 120 pounds body weight followed by 5 grams per ton to market weight.

(i) *Indications for use.* Increased rate of weight gain and improved feed efficiency.

(ii) *Animal weight.* For continuous use from weaning to market weight.

(5) *Amount per ton.* Administer 10 grams per ton from weaning to 120 pounds body weight followd by 5 to 10 grams per ton to market weight.

(i) *Indications for use.* Increased rate of weight gain and improved feed efficiency for swine up to 120 pounds body weight; increased rate of weight gain for swine from 120 pounds to market weight.

(ii) *Animal weight.* For continuous use from weaning to market weight.

§ 558.680 Zoalene.

(a) [Reserved]

(b) *Approvals.* Type A medicated articles: 25 percent to 017210 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Related tolerances.* See § 556.770 of this chapter.

(e) *Conditions of use.* (1) It is used for chickens and turkeys as follows:

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).	.....	Replacement chickens; development of active immunity to coccidiosis.	In grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.	

Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).

	Arsanilate sodium 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Arsanilic acid 90 (0.01%)	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As erythromycin thiocyanate; in grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; in grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
		2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 7 to 14 d; as erythromycin thiocyanate; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for good purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; and as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Arsanilate acid 90 (0.01%) plus penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation..	As procaine penicillin; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Bacitracin 100 to 500.....	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.	As bacotracom zomc; growther Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.	

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Chlortetracycline 100 to 200.	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride; grower Type C medicated feeds; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Chlortetracycline 200	Replacement chickens; control of synovitis; development of active immunity to coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride; in grower Type C medicated feeds; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As erythromycin thiocyanate; Grower Type C medicated feeds; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Erythromycin 92.5.	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
		Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis.	Feed for 7 to 14 d, withdraw 24 h before slaughter; as erythromycin thiocyanate; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Erythromycin 185	Replacement chickens; as an aid in the prevention and reductions of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; in grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.	
		Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
			Grams per ton	*Grams per ton*
		Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
		Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).
	Hygromycin B 8 to 12	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	In grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows;.	

Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).

Penicillin 2.4 to 50	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As procaine penicillin; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; as follows—.

Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).

Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.

Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).

Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In grower Type C medicated feed; not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; as follows—.

Growing conditions	Starter Type C medicated feed	Grower Type C medicated feed
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.01125%)	75.4–113.5 (0.0083%–0.0125%).
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%).

(iii) 113.5 (0.0125%)		Broiler chickens; prevention and control of coccidiosis	
	Arsanilate sodium 90 (0.1%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 days before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%)	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens; aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis.	do.
		2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; aid in the prevention of infectious coyza.	do.
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As penicillin procaine, withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus bacitracin 4 to 50.	Broiler chickens; prevention and control of coccidiosis; improving pigmentation; growth promotion and feed efficiency.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin methylene disslicylate.
	Bacitracin 4 to 50	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As bacitracin methylene disalicylate, or bacitracin zinc.
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to .005%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As bacitracin methylene disalicylate, or bacitracin zinc; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Bacitracin 100 to 500	Broiler chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention and control of coccidiosis.	As bacitracin zinc.
	Chlortetracycline 100 to 200.	Broiler chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis; prevention and control of coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.
	Chlortetracycline 200	Broiler chickens; prevention and control of coccidiosis; control of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.
	Erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As erythromycin thiocyanate.
	Erythromycin 92.5	1. Broiler chickens; aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate.
		2. Broiler chickens; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis.	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate.
	Erythromycin 185	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Hygromycin B (8 to 12)	Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).		
	Lincomycin 2	Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis.	Do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by 000009. in ; zoalene provided by 025700. in § 510.600(c) of this chapter.	
	Penicillin 2.4 to 50	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As penicillin procaine	
	Penicillin 2.4 to 50 plus roxarson 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as penicillin procaine.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic	
(m) 113.5 to 170.3 (0.0125% to 0.01875%).		Turkeys; prevention and control of coccidiosis	For turkeys grown for meat purposes only	
	Arsanilate sodium 90 (0.01%).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	For turkeys grown for meat purposes only; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%)	do	do	
	Carbarsone (Not U.S.P.) 227 to 340.5 (0.025% to 0.0375%).	Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead.	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	Withdrawn 5 d before slaughter; as sole source of organic arsenic	

(2) *Permitted combinations.* It may be used in accordance with provisions of this section in the combinations provided as follows:

(i) Bambermycins in accordance with § 558.95.

(ii) Roxarsone in accordance with § 558.530.

Interested persons may, on or before April 9, 1981, submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Dockets Management Branch (formerly the Hearing Clerk's office), Food and Drug Administration.

Dated: December 24, 1980.

Mark Novitch,

Acting Commissioner of Food and Drugs.

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